TECHNICAL REPORT

APPROVED: 13 June 2016

Outcome of the consultation with Member States and EFSA on the basic substance application for *Satureja montana* L. for use in plant protection as fungicide and bactericide on various crops

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for *Satureja montana* L. are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of *Satureja montana* L. as a basic substance for use in plant protection as fungicide and bactericide on various crops. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: *Satureja montana* L., basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2016-00217

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Summary

Satureja montana L. is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in March 2016, EFSA was asked to organise a consultation on the basic substance application for *Satureja montana* L., to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for *Satureja montana* L., organised by EFSA, was conducted with Member States via a written procedure in December 2015 - February 2016. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for *Satureja montana* L. essential oil and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Satureja montana L. (commonly known as winter savory or mountain savory) essential oil is a complex mixture of chemical substances obtained from the aerial parts of the plant by hydro-distillation. The main components of *Satureja montana* L. essential oil are: carvacrol, thymol, *p*-cymene, γ-terpinene and (β-)caryophyllene. The chemical composition depends on the place of geographical origin of the plant, but also on its stage of development and on climate conditions. The formulation made of *Satureja montana* L. essential oil is a dilution of the essential oil in cold water.

The proposed uses of *Satureja montana* L. essential oil are spray applications as a fungicide, bactericide on fruit trees, citrus, ornamentals, grapevine, tomato, potatoes, pepper, strawberry, tobacco, leaf vegetables and applications by injection/endotherapy and drip irrigation on fruit trees, date palm, chestnut and grapevine and also as post-harvest treatment on pome fruits and stone fruits. Details of the intended uses are presented in the GAP table in Appendix D.

Regarding the impact on human and animal health, adverse effects were reported on some of the components of *Satureja montana* L. in the literature including positive results in genotoxicity studies *in vitro* and *in vivo*, cholinesterase inhibition indicating neurotoxic activity, effects on blood coagulation, on ejaculation and on testosterone level in blood questioning a potential for endocrine disrupting activity. *Satureja montana* L. is expected to be harmful if swallowed (Acute Tox. 4, H302), and to cause severe skin burns and eye damage (Skin Corr. 1B, H314) based on the harmonised classification of thymol that may be present in the essential oil up to 46%. Additionally, EFSA's peer review found evidence that thymol may be a skin sensitiser (Skin Sens. 1, H317 'may cause an allergic skin reaction') that may also apply to *Satureja montana* L. As the toxicity profile of *Satureja montana* L. is not addressed, the need for setting toxicological reference values cannot be concluded on. Alternatively, robust human natural background exposure data from *Satureja montana* L. could be of value to compare non-dietary exposure through pesticide use, however these data are not available. Operator, worker, bystander and residential exposure risk assessment could not be concluded on.

Since adverse effects have been reported on some constituent components of *Satureja montana* L. and since the toxicity profile of *Satureja montana* L. could not be addressed and the need for setting toxicological reference values could not be concluded on, a consumer risk assessment related to the uses of *Satureja montana* L. essential oil as a plant protection product could not be completed.

In relation to the fate and behaviour into the environment, EFSA concluded that no reliable end points may be derived from the information provided for any of the biologically active components of *Satureja montana* L. Degradation end points in soil and surface water would need to be provided together with information on potential transformation products produced. Information on effect of photolysis in soil and water is also necessary, especially in relation to photoproducts of potential concern. In order to perform the groundwater risk assessment, information on the adsorption/ desorption of the different components to soil is also needed. When use of default end points or end points not based on direct experimental measurements is to be proposed, adequate justification would need to be provided. Consequently, EFSA has identified data gaps to address the environmental exposure assessment.

In the ecotoxicology section, some adverse effects caused by exposure to *Satureja montana* L. essential oil (or its component) were seen in birds, mammals, aquatic organisms, non-target arthropods, soil organisms and terrestrial plants. However, no risk assessment was presented for any of these non-target organisms. Furthermore, information on potential adverse effects of other major constituents of the essential oil was not submitted. Considering these two aspects, no conclusion can be drawn regarding the representative uses under evaluation.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/20091 (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Satureja montana L. is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l' Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as fungicide and bactericide on various crops.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for Satureja montana L., which was conducted via a written procedure in December 2015 - February 2016. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for Satureja montana L. and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of Satureja montana L. as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Institut Technique de l'Agriculture Biologique; 2016).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 14 March 2016, EFSA was asked to organise a consultation on the basic substance application for *Satureja montana* L., to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 14 June 2016.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for *Satureja montana* L. essential oil and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix C and D, respectively.

Documentation provided to EFSA

1. Institut Technique de l'Agriculture Biologique (ITAB), 2015. Basic substance application on *Satureja montana* L. submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2015. Documentation made available to EFSA by the European Commission.

2. Institut Technique de l'Agriculture Biologique (ITAB), 2016. Basic substance application update on *Satureja montana* L. submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2016. Documentation made available to EFSA by the applicant.

References

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance thymol. EFSA Journal 2012;10(11):2916, 43 pp. doi:10.2903/j.efsa.2012.2916.

ECHA (European Chemicals Agency), 2015. Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 4.1, June 2015. Reference: ECHA-15-G-05-EN; ISBN: 978-92-9247-413-3; available online: http://echa.europa.eu/documents/10162/13562/clp_en.pdf

ECHA (European Chemicals Agency), 2010. Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental exposure assessment, version 2.0, May 2010.

ECHA (European Chemicals Agency), 2016. Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental exposure assessment, version 3.0, February 2016.

Abbreviations

a.s.	active substance
CLP	Classification, Labelling and Packaging
DAR	draft assessment report
EC	emulsifiable concentrate
ECHA	European Chemicals Agency
GAP	good agricultural practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
MRL	maximum residue level
MS	Member State
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	pre-harvest interval
SC	suspension concentrate

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Satureja montana* L. and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
1(1)		DE: It is not agreed to approve *Satureja montana* L. essential oil as basic substance for several reasons: First, a relevant ingredient (up to 46 %) is the active substance thymol. For thymol classification R22, R34, R41 and R43 was proposed in result of the EU assessment (EFSA Journal 2012;10(11):2916). Second, the submitted data on *Satureja montana* L. essential oil indicate that some further ingredients are even more toxic than thymol with indications of genotoxicity, endocrine disrupting activity, sensitising activity and	EFSA: the toxicological profile of the a.s. should be characterised and an assessment of the risk associated with the use of substance should be performed (see chapter 5 on Impact on Human and Animal Health).	Although thymol has some classification it is included in annex IV (no MRL) for MRL (Reg. 396/2005). Botanical guidance document include in chapter §15 basic substance mention as outcome for plant extracts.	*Satureja montana* L. appears to be harmful if swallowed, corrosive and a skin sensitiser (see 4(1)). Adverse effects have been reported on different endpoints including genotoxicity, neurotoxicity and endocrine disrupting potential for some of its constituents. These effects should be clarified to address the toxicological profile of the essential oil and assess the need to set toxicological reference values and at which dose level. An alternative approach would be the measurement of natural background exposure data of humans to enable the conduct

General					
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		neurotoxicity. Thus, further toxicological information is needed. It is proposed that the application for authorisations of plant protection products containing *Satureja montana* L. essential oil should be based on the guidance document on botanical active substances (SANCO/11470/2012).			of a non-dietary risk assessment. Operator, worker, bystander and residential exposure risk assessment cannot be concluded on, based on the available data.

2. Identity of the substance/product as available on the market and predominant use

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		DE: No clear identity of the substance was submitted. The results on the composition vary strongly (e.g. the toxicologically relevant substance carvacrol was identified between 4 % and 75 %, the toxicologically relevant substance thymol was between 1 % and 46 %.) No standardised method of the preparation of the oil was submitted. A definition of a basic substance is not possible.		Considering natural substance extract, ranges are an ordinary situation. i.e. garlic extract is a PPP a.s. with unknown complete and variable composition.	Data gap: An unequivocal definition of the basic substance is needed. No clear identity of the substance was submitted. There is a large variation in the composition of the substance pending on its origin (e.g. the toxicologically relevant substance carvacrol was identified between 4 % and 75 %, the toxicologically relevant substance thymol was identified between 1 % and 46 %.) No standardised method for the preparation of the oil was submitted.
2(2)	2.1.2 CAS No	DE: The CAS No 8016-68-0 and EINECS No 616-987-1 should be deleted because they refer only to summer savory oil		Corrected	Addressed: The respective CAS and EINECS numbers were deleted.

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		(*Satureja hortensis)* and not to winter savory *(Satureja montana).*			
2(3)	2.1. IDENTITY AND PHYSICAL CHEMICAL PROPERTIES OF THE SUBSTANCE AND PRODUCT TO BE USED	ES: The main constituents of the *Satureja montana L*. essential oil seem vary greatly depending of the study. The reasons which conduct to this fact should be clarified and conditions to obtain the essential oil, avoiding this variation, should be established.	ES: No more comments	Restriction to unique provider would solve this question, but will be questionable regarding monopolistic situation.	Data gap: An unequivocal definition of the basic substance is needed with the corresponding specification.
2(4)	2.1.5. Description and specification of purity of the active substance and product	ES: The content of several constituents of essential oil should be clearly established, taking into account that they are currently approved as active substances (e.g. thymol, eugenol and geraniol).	ES: No more comments	Garlic extract before being an approved a.s. is of natural occurrence. Later, regarding Organic Production, single chemically synthetized molecules are not allowed but natural extract yes! So we do propose application for these natural extracts, including those containing single approved a.s. At first those a.s. are of natural occurrence and	Data gap: An unequivocal definition of the basic substance is needed with the corresponding specification.

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
				natural origin (botanicals or not). Approval of single chemically synthetized molecules (i.e. DMDS) contained in natural substances/plant may be not allowed anymore at Reg. 1107/2009? Pesticide industry is allowed to registered those for conventional farming, we don't contest this, but they will never be allowed in O.P.	
2(5)	2.1.1.	NL: It would be advisable to bring the name in line with reach guidelines for complex mixtures.	Essential oil of *Satureja montana L.* obtained from the aerial parts by hydro-distillation	Acknowledged, but this is the definition of E.O. before recent CO_2 extraction.	Addressed: In this technical report it is specified that the essential oil is obtained from the aerial parts of *Satureja montana* L. by hydro-distillation
2(6)	2.1.2 The principal constituents, p.8	EFSA: it seems that the composition of the oil is very variable, in Mastelic, Jerkovich an important constituent was thymol, while in Wesolowska, et al. it is not even mentioned.		Hydro distillation process applied to plant from different origin (harvesting time, location) may provide different E.O. so we provided a composition range. E.O. considered in our field	See data gaps in 2(3) and 2(4)

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
				experiments are guaranteed <15 % thymol (5.2 % indeed)	
2(7)	2.1.2 The principal constituents, p.8	EFSA: in Mastelic, Jerkovich it is mentioned that the oil contains eugenol, too. Was any attempt done to check for eventual amounts of methyl eugenol?	Methyl eugenol is a genotoxic carcinogen and a maximum level of 0.05 g/kg was set in the specification of eugenol, and for consistency of the risk assessment it is important to know if it *Satureja montana* L oil can contain it or no	No methyl eugenol is present in our E.O. From EFSA 2012 only one report of methyl eugenol: not confirmed Ref added Golgema 2012	Data gap: Confirmation of the absence of methyl eugenol The reference Golgema (2012) in the updated submission does not contain information about the methyl eugenol content. See also 5(15)
2(8)	2.1.2 Major constituents, p.10	EFSA: how it is possible to differenciate *Satureja montana* L oil from an oil from *Origanum majorana* L. for example? Without a specification of this oil the identification might be difficult. A specification of the five main components might be a solution, however it is also true that the chemical composition depends on the location of the plant but also on its stage of development		Not possible Confusion is observed in all EU.	Addressed: It is not possible to differentiate *Satureja montana* L oil from an oil from *Origanum majorana* L. Without a specification of this oil the identification might be difficult. A specification of the five main components might be a solution, however it is also true that the chemical composition depends on the location of the plant but also on its stage of development and climate

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		and climate conditions.			conditions.
2(9)	2.1.5 Specification of the purity of the a.s. and product. P.12	EFSA*: Satureja montana* L. essential oil is extracted from the aerial parts is considered the formulation and statements are made about its properties, without supporting data.	A 4 years of shelf life is claimed without any supporting data of the content of the constituent components and physical and chemical properties before and after storage.	Storage claim supressed. Was informative. Not useful for this application.	Addressed: The statement for the storage stability was removed from the submission.
2(10)	2.1.5 Specification of the purity of the a.s. and product. P.12	EFSA: was the statement of not highly flammable and not auto-flammable based on studies?	A study or a case should be submitted to support the statement.	Properties considered for product in water, removed.	Addressed: The statement was based on considering the product in water.

2.2. Current Former and in case proposed trade names					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments.

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
No comments.					

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(11)		EFSA: were the properties of an EC formulation checked?	Usually for an EC formulation the following minimum properties are indicated: emulsion stability, persistent foam, law and high temperature storage stability	Modified	Data gap: Technical properties for the SC formulation (Usually for an SC formulation the following minimum properties are indicated: pourability, spontaneity of dispersion, suspensibility, wet sieve test, persistent foam, low and high temperature storage stability). Technical properties for the EC formulation (for an EC formulation the following minimum properties are indicated: emulsion stability, persistent foam, law and high

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					temperature storage stability) The formulation type was modified from EC to SC, but not in the GAP table.

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments.

3. Uses of the substance and its product

3.1. Field of use					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature leaves the mode of action unclear. Overall, only limited effect in the uses described should be expected.	DE: In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exist.	Comment rejected, literature provided and Casdar HE field trial added	Addressed: Additional literature reference was added (Casdar HE).

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(2)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	DE: Please provide reasons for your opinion that no phytotoxicity must be expected.	Publication Casdar HE Alter Agri added	Data gap: The potential phytotoxic effects were not addressed. The provided publications do not contain data addressing phytotoxicity.
3(3)	3.4 Summary of	ES: It should be corrected the units		Colum 3 corrected in	Addressed:

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	intended uses	appearing in the headline (title) -Application rate per treatment: kg instead of g		Application rate per treatment	The unit was corrected.
3(4)	3.4 Summary of intended uses	ES: Some values in the table are wrong Please review *Application rate per treatment* and *Total rate* for Date palm and Chestnut		checked	Data gap: The GAP table for date palm still needs to be corrected for the maximum application rate per treatment expressed as kg a.s./ha
3(5)	3.4 Summary of intended uses	ES: A line with all the information regarding post-harvest application should be included in the GAP Table		GAP changed	Data gap: A row with all the information regarding post-harvest application should be included in the GAP table if it is claimed as a supported use.
3(6)	3.4 Summary of intended uses	ES: In Remarks (Foliar application spraying); the phrase should be corrected as following: "The mix with essential oil must be used 24 h MAXIMUM after preparation"		Acknowledged.	Data gap: The GAP table should be corrected to: 'The mix with essential oil must be used within 24 h after preparation'

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)		DE: *Satureja montana* L. essential oil contains up to 46 % thymol. For thymol the following classification was proposed (EFSA Journal 2012;10(11):2916): R22, R34, R41 and R43. The submitted data indicate additional relevant toxic properties of further ingredients. Additional data on toxicity are needed.	EFSA: see chapter 5 (impact on human and animal health)	Thymol and eugenol have no classification in EU pesticide database and are included in annex IV (no MRL) for MRL (Reg. 396/2005). Same for geraniol. How is this compatible with such toxicological classifications? Only Guideline 11188/2013 may explain such issue, especially chapter 3.3.1.	Harmonised classification of thymol according to Regulation (EC) 1272/2008[2] (CLP Regulation) includes the following classes: Acute Tox. 4, H302 'harmful if swallowed' and Skin Corr. 1B, H314 'causes severe skin burns and eye damage'. Besides, the EFSA peer review found evidence that thymol may be a skin sensitiser (Skin Sens. 1, H317 'may cause an allergic skin reaction'[3]) (EFSA, 2012). These classifications are applicable to *Satureja montana* L. as it may contain up to 46% thymol (ECHA, 2015). Additionally, other toxicological properties of the extract have

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[3] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					not been addressed (see 5(8)(11)(14)(16) on genotoxicity, neurotoxicity, reproductive and potential endocrine disruption).
4(2)		PL: ECHA classification in progress			Harmonised classification is established for 'thymol'; notified classifications are reported for 'Thyme, Thymus vulgaris ext.' (notified classification to ECHA according to CLP criteria).

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(1)	Tisserand, R., & Young, R. 2013	PL: Reference not relevant	Please remove	Removed	Noted.
5(2)	Stanic, G., &	PL: Reference not relevant	Please remove it from this	Moved	Noted.

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	Samaržija, I. 1993		subchapter and insert in the subchapter 5.10.1.		
5(3)	Toxnet U.S National Library of Medicine Toxicology data network. As of june 2015 P-cymene	PL: Reference not relevant	Please remove it from this subchapter and insert in the subchapter 5.2.	Moved	Noted.

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)		DE: The submitted data indicate that some of the ingredients are sensitising. For thymol classification of sensitising activity was proposed (EFSA Journal 2012;10(11):2916). Further information is needed.	EFSA: Toxicity information should be submitted to characterise acute toxicity, skin and eye irritation and skin sensitisation potential of the active substance.	Toxic but approved as a.s. with no classification and no MRL. Again chapter 5.10 and 5.11 not empty, please remove all food uses if such toxicity is proven.	See 4(1); with the available data, the product should be considered as a skin sensitiser.
5(5)	Stammati, A. et al., 1999	PL: Reference relevant to acute toxicity and short-term toxicity	Please insert this publication additionally in the subchapter 5.3.	Moved	Noted.

5.2. Acute toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(6)	Gad, M.M.E.S, 2012	PL: Reference relevant to acute toxicity and short-term toxicity	Please insert this publication additionally in the subchapter 5.3.	Moved	Noted.

5.3. Short-term toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**		**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(7)	Xu, J. et al., 2008	PL: Reference not relevant	Please remove it	Removed	Noted.

5.4. Genotoxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(8)		DE: Some of the submitted studies report genotoxic activity of ingredients: Carvacrol caused nuclear fragmentation and was dose-dependently genotoxic in bone marrow cells of rats. Thymol caused	EFSA: the genotoxic potential of the active substance has to be addressed.	Toxic but approved as a.s. with no classification and no MRL.	Data gap: Positive genotoxicity tests *in vitro* and *in vivo* were reported with components of *Satureja montana* L. therefore the genotoxic potential of the

5.4. Genotoxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		clastogenicity in two *in vitro* assays and caused increased chromosome aberrations in rats *in vivo*. Gamma-terpinene was genotoxic, causing significant increases in DNA damage. Therefore, further data on genotoxicity are needed. An approval as basic substance is not justified.			essential oil has to be addressed.

5.5. Long-term toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(9)	Bakkali, F. et al., 2008	PL: Not sufficient data	Please remove this reference	Removed	Noted.

5.6. Reproductive toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(10)	Momtaz, S., & Abdollahi, M. 2010	PL: Reference not relevant	Please remove it from this subchapter and insert in the subchapter 5.13	Moved	Noted.

5.7. Neurotoxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 4** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(11)		DE: According to the submitted studies 3 different oils of *Satureja montana* caused cholinesterase inhibition. Therefore, a neurotoxic activity is indicated. Furthermore, according to the submitted information *Satureja montana* oil can cause drowsiness and sedation in humans. Thymol reduced motor activity and ataxia was identified following gavage.	EFSA: the neurotoxic potential of the active substance has to be addressed.		Data gap: As neurotoxic activity (cholinesterase inhibition) has been observed with 3 different oils of *Satureja montana* L., its neurotoxic potential has to be addressed.

5.7. Neurotoxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 4** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		These effects are further indications of a possible neurotoxic activity. Further information is needed.			
5(12)	Azirak, S., & Rencuzogullari, E. 2008	PL: Reference not relevant	Please remove it from this subchapter and insert in the subchapter 5.4	Moved	Noted.

5.8. Toxicity studies on metabolites					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(13)	All data	PL: Not relevant	Remove all, please		Noted.

5.9. Medical Data: adverse effects reported in humans					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(14)		DE: The *Satureja montana* oil causes increased risk of bleeding. Ingredients of the oil	EFSA: the toxicological profile (at least short term) of the active substance has to be addressed.		Data gap: Adverse effects may be expected from *Satureja*

5.8. Toxicity studies on metabolites					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		cause antiplatelet aggregation activity. These effects are relevant for human health. Further information is needed.			*montana* L. exposure such as reduced blood coagulation. To address this issue, at least a short term toxicity study should be conducted.
5(15)	5.9 (Tisserand, & Yount 2013 reference)	NL: In this reference it is stated that winter savory essential oil may contain methyleugenol. However, in section 2.1.2 no mention is made of this. Since methyleugenol is a genotoxic carcinogen it is important to know if it is present in the product and if so to what extent.	EFSA: carcinogenic potential of the active substance has to be addressed (see also comment 5(10) regarding genotoxicity)	No methyl Eugenol in analysis of winter savory essential oil provided §2	See 2(7)

5.10. Additional Information related to therapeutic properties or health claims					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(16)		DE: Zavatti et al., (2011) reported effects of the *Satureja*	EFSA: the toxicity for reproduction and development, as well as the		Data gap: As adverse effects have been

5.10. Additional Information related to therapeutic properties or health claims					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		montana oil on ejaculation and on testosterone level in blood. These are possible indications of endocrine disruption. Further information is needed.	endocrine disrupting properties of the active substance have to be addressed.		reported on the reproductive system (ejaculation and testosterone level in blood), reproductive and developmental toxicity, as well as endocrine disrupting properties of *Satureja montana* L. have to be clarified.

5.11. Additional information related to use as food					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
No comments.					

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(17)	5.12	NL: Reference values are given for	EFSA: considering the toxicological		Data gap:

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		winter savory essential oil and for thymol. It would be useful to include an exposure assessment to compare the exposure resulting from use as a basic substance with these reference values.	profile of the substance, the need to set reference values should be considered. An exposure assessment should then be performed.		As the toxicity profile of *Satureja montana* L. is not addressed, the need for setting toxicological reference values cannot be concluded on. Alternatively, measurements of human natural background exposure data from *Satureja montana* L. could be of value, but are not available. Operator, worker, bystander and residential exposure risk assessment has not been addressed.

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(18)	Flamini, G., & Cioni, P. L. 2003 (page 32 of this document)	PL: Reference refers to animal health	Please insert the reference to this subchapter	Added	Noted.

PL:
Comment to Conclusion §5: Taking into account the list of intended uses and the suggestion of skin irritant and skin allergic effects of savory and its constituents it would be worth to emphasise the possibility of operator risk towards undiluted formulation.

6. Residues

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
6(1)	6.	NL: Reference could be made to EFSA's Peer Review of thymol (EFSA Journal 2012;10(11):2916), in which supervised residue trials with thymol are described. Furthermore, the consumer risk assessment could not be conducted during the peer review. However, in the current report, reference values are described for thymol. Therefore, a dietary risk assessment could now be performed.		Ref added	Reference to EFSA's Peer Review of thymol (EFSA, 2012) has been added in the updated application.
6(2)		EFSA: Pending the conclusion on the toxicological profile of the different constituent components of *Satureja montana.L.* essential oil, further data might be requested.			As the toxicity profile of *Satureja montana* L. was not addressed (see point 5(17)) and the need for setting toxicological reference values could not be concluded on, a consumer risk assessment

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					related to the uses of *Satureja montana* L. essential oil as a plant protection product could not be completed.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	3.4 Summary of intended uses.	EFSA: It is noted that application rates up to 12 Kg /ha are proposed for some intended uses being 6 kg / ha frequent for many of them. Corresponding application rates for the individual components with known biological activity would need to be calculated to perform the environmental exposure assessment (i.e. PEC soil, PEC SW/sed, PEC GW).	Corresponding application rates for the individual components with known biological activity would need to be calculated to perform the environmental exposure assessment (i.e. PEC soil, PEC SW/sed, PEC GW).	GAP table modified, rates reduced drastically.	Data gap Application rates for the individual components with known biological activity need to be calculated based on proposed representative uses (up to 6 kg / ha in the updated table). Applicant to perform the environmental exposure assessment for the individual components with known biological activity based on proposed uses (i.e. PEC soil, PEC SW/sed, PEC GW).
7(2)	7.1.1 Carvacrol. EFSA Panel on Additives and products or Substances used in Animal Feed	EFSA: Risk assessment in this opinion is based on maximum worst case PEC soil of 16-27 µg / kg and PEC SW < 10 µg / L, with the added assumption that these levels will never be			See data gap in 7(1).

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	(FEEDA). 2015 Scientific opinionon the safety and efficacy of XTRACT® Evolution –B (carvacrol, cinnamaldehide and capsicum oleoresin) as a feed for chickens for fattering. *EFSA Journal 2015; 13(2):4011.*	reached in the environment under realistic conditions due to the metabolization of carvacrol by the chickens. Therefore, this risk assessment cannot be used as a surrogate of the necessary assessment as pesticide where about up to 6 Kg carvacrol may be directly released to the environment as a consequence of the maximum application rate proposed for Satureja Montana L.			
7(3)	7.1.1 van Roon, A., Parsons, J. R., te Kloeze, A. M., & Govers, H. A. 2005 Fate and transport of monoterpenes through soils. Part I. Prediction of temperature dependent soil fate	EFSA: information provided by this paper is only qualitative and does not allow performing a quantitative exposure assessment.	Reliable information on route and rate of degradation in the different environmental compartments of the known biological active components of Satureja Montana L should be provided. In addition information on their adsorption and mobility in soil is needed. It is noted that if reliable readily biodegradability study was		Data gap Reliable information on route and rate of degradation in the different environmental compartments of the known biological active components of *Satureja montana* L. needs to be

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	model input-parameters. Chemosphere, 61(5), pp599-609.		available for the individual components, then the default values as proposed in REACH guidance (ECHA, 2010) could be used in a first tier worst case environmental exposure and risk assessment. For the ECHA guidance see: ECHA (European Chemicals Agency), 2016. Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental exposure assessment, version 3, February 2016. In particular pay attention to: A.16-3.2.2 Degradation rates in the environment Tables R16-11 and R16-12.		provided. In addition information on their adsorption and mobility in soil is needed. It is noted that, if a reliable readily biodegradability study was available for the individual components, then the default values as proposed in REACH guidance (ECHA, 2010) could be used in a first tier worst case environmental exposure and risk assessment. For the ECHA guidance see: ECHA, (2016). Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental exposure assessment, version 3, February 2016. In particular pay attention to: A.16-3.2.2

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					Degradation rates in the environment Tables R16-11 and R16-12. For those components in *Satureja montana* L. already evaluated by EFSA as plant protection active substances, please refer to respective EFSA conclusion and address issues identified there. In case applicant wishes to use information collected in secondary scientific sources (eg. Toxnet U.S National Library of Medicine Toxicology data network) for any particular component (eg *p*-cymene), the relevant raw studies quoted there would need to be provided and assessed.
7(4)	7.1.2 Thymol	EFSA: Vol 1 of draft assessment of	For those components in *Satureja*	Actually, EFSA evaluation is not	See data gap in 7(3)

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	Draft Assessment Report (DAR), 2011. THYMOL of the review programme referred yo in Article 8(1) of Council Directive 91/414/EEC, Volume 1, Level 2, pp20-29	Thymol should be considered superseded by EFSA conclusion on the active substance Thymol: -European Food Safety Authority; *Conclusion on the peer review of the pesticide risk assessment of the active substance thymol. EFSA Journal 2012;10(11):2916. [43 pp.]* doi:10.2903/j.efsa.2012.2916. It is noted that EFSA concluded that no reliable data or information had been submitted on the route and rate of degradation of thymol in soil. For the exposure assessment of the parent thymol, it was accepted that worst case default DT50 following REACH guidance (ECHA, 2010) will result in a sufficiently conservative	*montana* L already evaluated by EFSA as plant protection active substances, please refer to EFSA conclusion and address issues identified there. However, be aware that some information there in may be owned by specific PP active substances applicants and data protection rights would need to be adequately considered before using that information in the assessment of *Satureja montana* L.	clear. First sentence: No reliable data or information have been submitted on the route and rate of degradation of thymol in soil. Second sentence: Since thymol is readily biodegradable, and based on its chemical structure, the waiver for the route of degradation in soil was accepted. No link, no scientific proof, complete inverse sense in the 2 sentences, but synthetic compound approved…	

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		assessment. A DT50 = 30 d (Default according REACH guidance for readily biodegradable substances with a Kd < 100 mL/g) was agreed by the peer review. It is noted that for Thymol with a max appl. rate of 260 g/ha and on the basis of the available data, EFSA identified a critical area of concern for groundwater exposure by thymol above the parametric drinking water limit of 0.1 µg/L is predicted over a wide range of geoclimatic conditions. It is emphasized that the proposed uses for *Satureja montana* L. will result on equivalent or higher exposure to thymol than those evaluated for the active substance thymol.			
7(5)	7.1.3 *p*-cymene	EFSA: In case applicant wants to use data quoted in Toxnet U.S			See data gaps in 7(1) and 7(3)

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
	Toxnet U.S National Library of Medicine Toxicology data network. As of june 2015 P-cymene	National Library of Medicine Toxicology data network to address the environmental exposure of p-cymene in Satureja Montana L, the relevant raw studies quoted there would need to be provided and assessed. As presented, information in the summary can only be considered in qualitative terms and not useful to perform the necessary environmental exposure and risk assessment.			
7(6)	7.1.4 γ-terpinene	EFSA: Origin of the qualitative information provided not reported. Information not useful to perform the necessary environmental exposure and risk assessment.			See data gaps in 7(1) and 7(3)
7(7)	7.1.5. (β)-caryophyllene.	EFSA: No data provided. Information on fate and behaviour into the environment would need to be	EFSA: In conclusion, no reliable fate and behaviour end points may be derived from the information provided for any of the		See data gaps in 7(1) and 7(3)

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		provided perform the necessary environmental exposure and risk assessment.	biologically active components of Satureja Montana L. At least degradation end points in soil and surface water would need to be provided together with information on potential transformation products produced. Information on effect of photolysis in soil and water is also necessary, especially in relation to photoproducts of potential concern. In order to perform the groundwater risk assessment information on the adsorption/ desorption of the different components to soil is also needed. When use of default end points or end points not based on direct experimental measurements is to be proposed, adequate justification should be provided (eg on basis of FOCUS guidance, Guidance on information requirements and		

7.1 Fate and Behaviour in the environment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
			chemical safety assessment. Chapter R.16: Environmental exposure assessment, version 3, February 2016 or EPISuit™ QSAR estimates etc…)		

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(8)	7.2. ESTIMATION OF THE SHORT AND LONG-TERM EXPOSURE OF RELEVANT ENVIRONMENTAL MEDIA (SOIL, GROUND WATER, SURFACE WATER)	EFSA: Predicted environmental concentrations of the different biological active components of Satureja Montana L in the different environmental compartments (soil, surface water, sediment and ground water) resulting from the intended uses proposed need to be provided.	EFSA: Please, use FOCUS guidance for the determination of the corresponding PECs. See: http://esdac.jrc.ec.europa.eu/projects/focus-dg-sante		See data gap in 7(1)

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1.1. Birds	DE: *S. khuzistanica* oil lowered feed intake and suppressed weight gain in chicks during the early growth periods. This may cause unacceptable effects on birds.	DE: Show in a sound risk assessment that there is not an unacceptable risk for birds caused by the intended uses.		Data gap No risk assessment was presented for any non-target organisms despite some data were available.
8(2)	8.1. EFFECTS ON TERRESTRIAL VERTEBRATES	EFSA: The cited EFSA opinion is not relevant in the present situation. In that case, the exposure assessment was based on the excretion of the considered substances given to livestock within foodstuff. In this case, carvacrol is applied directly to the field within the essential oil.	EFSA: either delete the reference or highlight the non-relevance of the conclusion ("safe for the environment") for the present submission.		See data gap in 8(1).
8(3)	Khosravinia et al. (2013)	EFSA: effects on birds were seen at 0.5 g/L in drinking water.	EFSA: as exposure estimation is possible, carry out a proper risk assessment.		See data gap in 8(1).
8(4)	Flamini et al. (2003)	EFSA: only a table without any context was provided in the dossier. No useful information	EFSA: either provide the full book chapter/section or delete the reference.		See data gap in 8(1).

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		can be drawn.			
8(5)	George et al. (2010) and Castillejos et al. (2008)	EFSA: No useful information is contained in the paper for assessing potential adverse effects on mammals. This is a laboratory test were mammals were not even present.	EFSA: remove the reference or highlight the non-relevance of the findings.		See data gap in 8(1).
8(6)	Puotinen (2008)	EFSA: Absolutely inappropriate information. Not coming from a peer-review paper nor from a scientific source.	EFSA: remove reference.	Only false data are inappropriate. For peer review and scientific sources, EFSA do not allowed them anyway.	See data gap in 8(1).
8(7)	Stanic, G., & Samaržija, I. 1993	EFSA: toxic effects were seen on rats at high dosage.	EFSA: use information for carrying out some kind of risk assessment.	3.5 L of solution per human, more than recommended daily water volume.	See data gap in 8(1).
8(8)	8.1.2.1. Carvacrol toxnet	EFSA: indication of tox effects to mouse and rabbits.	EFSA: use information for carrying out some kind of risk assessment.		See data gap in 8(1).
8(9)	8.1.2.2. Thymol	EFSA: In the thymol DAR, a valid long term endpoint was reported for mammals. Why this endpoint was not used for carrying out a risk assessment in this case?	EFSA: use information for carrying out a risk assessment.	If toxic, endocrine disruptor and genotoxic, why it is still an approved active substance? Remove it from PPP.	See data gap in 8(1).
8(10)	8.1.2.3. p-cymene	EFSA: Relevant endpoints are	EFSA: consider the studies included		See data gap in 8(1).

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	toxnet	reported on this page. Why the studies contained therein were not evaluated and the relevant endpoints were not used in a risk assessment?	in the page, (if possible evaluate them) and use the results in the risk assessment		
8(11)	General	EFSA: it is clear that Satureja montana essential oil and its components may exert some toxic effect to terrestrial vertebrates. However, in the present submission, such effects were not considered in a risk assessment framework. It is noted that the amount of essential oil to be applied according to the GAP is very high (up to 12 kg/ha x 12 applications), therefore adverse effect on wild populations of birds and mammals cannot be excluded. No conclusion on the actual risk posed by the intended uses could be drawn without any consideration on the risk	EFSA: perform some kind of risk assessment. No assessment could be finalised at the present stage.	Quantities reduced after field trials results.	See data gap in 8(1).

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		assessment.			
8(12)	General	EFSA: information on the potential adverse effect of some major constituents of the essential oil was not submitted.	EFSA: provide information for addressing the risk to birds and wild mammals.		Data gap Information on the potential adverse effect of some major constituents of the essential oil was not submitted

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13)	Ibid.	DE: The described insecticidal effect of *S. montana* essential oil may cause unacceptable effects on aquatic invertebrates.	DE: Show in a risk assessment that there is no unacceptable risk for aquatic invertebrates caused by the intended uses.		See data gap in 8(1).
8(14)	8.2. EFFECTS ON AQUATIC ORGANISMS	EFSA: Relevant endpoints are presented in the thymol DAR and in the TOXnet for p-cymene. Why these endpoints were not used in a standard risk assessment?	EFSA: perform a risk assessment.		See data gap in 8(1).

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(15)	General	EFSA: it is clear that Satureja montana essential oil and its components may exert some toxic effect to aquatic organisms. However, in the present submission, such effects were not considered in a risk assessment framework. It is noted that the amount of essential oil to be applied according to the GAP is very high (up to 12 kg/ha x 12 applications), therefore adverse effect on aquatic populations cannot be excluded. No conclusion on the actual risk posed by the intended uses could be drawn without any consideration on the risk assessment.	EFSA: perform some kind of risk assessment. No assessment could be finalised at the present stage.	Quantities reduced after field trials results.	See data gap in 8(1).
8(16)	General	EFSA: information on the potential adverse effect of some major constituents of the essential oil was not submitted.	EFSA: provide information for addressing the risk to aquatic organisms.		Data gap Information on the potential adverse effect of some major constituents of the essential oil

8.2. Effects on aquatic organisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					was not submitted.

8.3. Effects on bees and other arthropods species					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(17)	3.2.1.3. Insecticidal activity and 3.2.1.4. Repellency activity	DE: An insecticidal and acaricidal activity as well as an activity as a repellent may cause unacceptable effects on non-target arthropods. The presented data are not appropriate to assess the risk to bees.	DE: Show in a sound risk assessment that the intended uses cause no unacceptable risk on non-target arthropods. Please indicate in dossier.		See data gap in 8(1).
8(18)	8.3.1. Effect on bees	DE: Doses ranging from 2.5 to 20 µL caused an unacceptable level of bee mortality. It does not become clear from the information given in the application whether these concentrations will be reached	DE: Show in a sound risk assessment that the intended uses cause no unacceptable risk on non-target arthropods.	*S. montana* honey is collected by bees and commercially available, so how this can be possible?	See data gap in 8(1).

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		by the intended uses. No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	Please indicate in dossier.		
8(19)	8.3.1	NL: is het possible to elaborate on the conclusion on winter savory in the study of Nedic *et al.* 2013 related to the use of Satureja Montana I?			See data gap in 8(1).
8(20)	8.3.1. Effects on bees	EFSA: Effects to honeybees were reported in the thymol DAR. These endpoints may have been used for a risk assessment.	EFSA: perform a risk assessment.		See data gap in 8(1).
8(21)	Nedic et al. (2013)	EFSA: Relevant endpoints were presented in this study. Why these endpoints were not used in a risk assessment?	EFSA: perform a risk assessment.		See data gap in 8(1).
8(22)	Vidic et al. (2009)	EFSA: information reported in this study are not useful for any risk assessment.	EFSA: either remove the reference or highlight the lack of relevance for the risk		See data gap in 8(1).

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			assessment.		
8(23)	Thymol DAR	EFSA: The risk assessment presented in the thymol DAR is not overlapping with the present risk assessment, as the application amount is very different. The GAP considered in the thymol DAR were: 4 application of max 0.26 kg a.s./ha. In the present submission, if we consider the maximum % of thymol found in the essential oil (46%, Mastelić, J., & Jerković, I. 2003), the GAP would consist of 12 applications of 5.5 kg a.s./ha each (worst case - application to pears). We wonder why the endpoints contained in the DAR were not used to carry out a novel risk assessment in accordance with the present GAP.	EFSA: carry out a novel risk assessment in accordance with the relevant GAP.	Quantities and number of applications are reduced in GAP after field trials results.	See data gap in 8(1).
8(24)	General	EFSA: it is clear that Satureja montana essential oil and its	EFSA: perform some kind of risk assessment. No assessment	Quantities and number of applications are reduced in GAP	See data gap in 8(1).

8.3. Effects on bees and other arthropods species					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		components may exert some toxic effect to bees and other arthropod species. However, in the present submission, such effects were not considered in a risk assessment framework. It is noted that the amount of essential oil to be applied according to the GAP is very high (up to 12 kg/ha x 12 applications), therefore relevant adverse effect cannot be excluded. No conclusion on the actual risk posed by the intended uses could be drawn without any consideration on the risk assessment.	could be finalised at the present stage.	after field trials results.	
8(25)	General	EFSA: information on the potential adverse effect of some major constituents of the essential oil was not submitted.	EFSA: provide information for addressing the risk to bees and other arthropod species.		Data gap Information on the potential adverse effect of some major constituents of the essential oil was not submitted.

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(26)	3.2.1.6. Nematicidal activity	DE: A nematicidal activity may cause unacceptable effects on earthworms. Robust experimental studies carried out with relevant soil macro organisms (e.g. the standard test earthworm *Eisenia fetida*) were not submitted.	DE: Show in a sound risk assessment that the intended uses cause no unacceptable risk on earthworms. Please indicate in the dossier		See data gap in 8(1).
8(27)	Livingstone (1921)	EFSA: This paper shows clearly that a toxic effect to earthworms is exerted by both thymol and carvacrol. We acknowledge that no useful endpoint could be derived from this study, however, there is evidence that toxicity to earthworms should be considered.	EFSA: use available data to carry out some kind of risk assessment.		See data gap in 8(1).
8(28)	Thymol DAR	EFSA: Relevant endpoints are presented in the thymol DAR. Why these endpoints were not used in a standard risk	EFSA: perform a risk assessment.		See data gap in 8(1).

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		assessment?			
8(29)	General	EFSA: it is clear that Satureja montana essential oil and its components may exert some toxic effect to soil organisms. However, in the present submission, such effects were not considered in a risk assessment framework. It is noted that the amount of essential oil to be applied according to the GAP is very high (up to 12 kg/ha x 12 applications), therefore relevant adverse effect cannot be excluded. No conclusion on the actual risk posed by the intended uses could be drawn without any consideration on the risk assessment.	EFSA: perform some kind of risk assessment. No assessment could be finalised at the present stage.	Quantities and number of applications are reduced in GAP after field trials results.	See data gap in 8(1).
8(30)	General	EFSA: information on the potential adverse effect of some major constituents of the essential oil was not submitted.	EFSA: provide information for addressing the risk to soil organisms.		Data gap Information on the potential adverse effect of some major constituents of the essential oil

8.4. Effects on earthworms and other soil macroorganisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					was not submitted.

8.5. Effects on soil microorganisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(31)	3.2.1.1. Fungicidal activity and 3.2.1.2. Bactericidal activity	DE: Due to the described fungicidal and bactericidal activity of *S. montana* essential oil effects on soil microorganisms because of the intended uses are possible. No robust experimental reports were submitted from which information about effects on soil micro-organisms can be derived.	DE: Show in a risk assessment that there are no unacceptable effects on soil microorganisms caused by the intended uses. Please indicate in the dossier.		See data gap in 8(1).
8(32)	General	EFSA: no risk assessment is presented.	EFSA: either perform a risk assessment or use sound scientific justification for demonstrating that the risk assessment could be waived.		See data gap in 8(1).

8.5. Effects on soil microorganisms					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
			No assessment could be finalised at the present stage.		

8.6. Effects on other non-target organisms (flora and fauna)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(33)	Ibid.	DE: Constituents of *S. montana* inhibited the germination of weeds and crops. *S. montana* essential oil has an herbicidal effect. This may cause unacceptable effects on non-target plants.	DE: Show in a risk assessment that there is not an unacceptable risk on non-target arthropods caused by the intended uses.	Not intended for weed control, not allowed in organic Production.	See data gap in 8(1).
8(34)	Angelini et al. (2003) and Grosso et al. (2010)	EFSA: Both studies showed that savory essential oil has a very strong effect on all tested species, inhibiting germination and shoot growth. These effects are likely to have an impact on NTTP when the essential oil is sprayed on	EFSA: perform a risk assessment. No assessment could be finalised at the present stage.		See data gap in 8(1).

8.6. Effects on other non-target organisms (flora and fauna)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		crops. This issue should be tackled with a proper risk assessment.			

8.7. Effects on biological methods of sewage treatment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		DE: If such precautions are necessary, can *Satureja montana* oil be considered as not being a substance of concern and hence be assessed as a basic substance?		How many substances of concern including non-approved basic substances sold as Pflanzenstärkungsmittel ?	This is a risk management decision.
9(2)	General comment	ES: The fulfilment of the criterion "(d) is not placed on the market as a plant protection product" is questionable, since several of the essential oil constituents are currently approved as active substances (e.g. thymol, eugenol and geraniol) and their content could be high (please, see comments above for issue 2.1 and 2.1.5). This criterion should be guaranteed by establishing requirements that assurance the absence of	ES: No more comments	We understand the fact that individual molecules contained in the *Satureja montana* E.O. are synthetic a.s. approved, but as synthetic, they would not be accepted in organic production. Again it is currently envisaged to be used as disinfectant in organic production as well (EGTOP/2016). Overuses of single synthetic molecules give rise to many resistances cases in phytopharmacy, biocides and animal health as well. Such	This is a risk management decision.

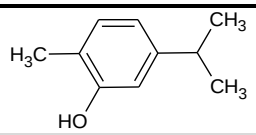
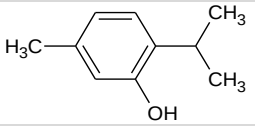
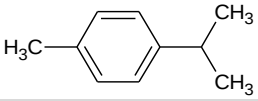
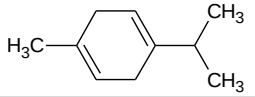
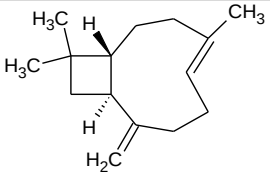
Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		these constituents in the *Satureja montana L.* essential oil.		destructive evaluation is a nonsense.	

10. Other comments

Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		DE: General comment on the efficacy evaluation in the dossier: the idea of the authorisation of basic substances is that no product approval takes place after the final decision on the basic substance.	DE: Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur.	No more comment from applicant. flanzenstärkungsmitteln are non-approved and illegal PPPs!	See comment 3(1)

Appendix B – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
Carvacrol	5-isopropyl-2-methylphenol Cc1ccc(cc1O)C(C)C	
Thymol	thymol CC(C)c1ccc(C)cc1O	
p-cymene	1-isopropyl-4-methylbenzene Cc1ccc(cc1)C(C)C	
γ-terpinene	1-isopropyl-4-methylcyclohexa-1,4-diene CC1=CCC(=CC1)C(C)C	
(β-)caryophyllene	(1*R*,4*E*,9*S*)-4,11,11-trimethyl-8-methylenebicyclo[7.2.0]undec-4-ene C=C2CCC=C(C)CC[C@@H]1[C@@H]2CC1(C)C	

Appendix C – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture
Chemical name (CA)	Not relevant, the substance is a complex mixture
Common names	Winter savory or mountain savory oil
CAS No	90106-57-3 (*Satureja montana* L. oil)
CIPAC No and EEC No	290-280-2 (EINECS/ELINCS)
FAO specification	Not available
Minimum purity	Purity is depending on the origin
Relevant impurities	Open
Molecular mass and structural formula	Not relevant, the substance is a complex mixture
Mode of Use	Spray applications, drip irrigation, injection
Preparation to be used	Suspension concentrate (SC) Emulsifiable concentrate (EC)
Function of plant protection	Fungicide, bactericide

Appendix D – List of uses

Foliar spraying

Crop and/or situation (a)	Member State	Product Name	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (l)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season ** (j)	Number min max (k)	Interval Between applications (min) (Days)	g a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (*) (kg/ha)	kg a.i./ha min max (kg/ha) (l)		
Pear tree *Pyrus communis*	not relevant France & All Member states	Solution of essential oil of *Satureja montana L.*	F	Pear scab *Venturia pirina*	SC Suspension concentrate	2 (0.2%)	Foliar application spraying	BBCH 53 to 54	1 to 4	7	200	500	1	1 to 4	15 to 30	The mix with essential oil must be used 24h after preparation
Apple tree *Malus sp.*				Apple scab *Venturia inaequalis*												
Citrus, eucalyptus, ornemental plants like *hydrangeas*, *camellias*, *Nerium oleander*.				*Fumagine Capnodium oleaginum or Fumago silicina*		0.67 (0.06%)		When biting sucking insects : aphids, mealybugs and *Metcalfa Pruinosa* drop off honeydew	1 to 12	7	67	150	0.1	0.1 to 1.2		
Grapvine *Vitis vinifera*				Mildew *Plasmopara viticola*		0.67 to 2		BBCH 12	1 to 4	7 to 10	67 to 200	150 to 300	0.1 to 0.6	0.6 to 2.4		

Vegetables gardening Potatoes *Solanum Tuberosum*						(0.06 to 0.2%)		BBCH 11 to29						0.1 to 3.6	7	
Gardening Tomato *Solanum lycopersicum*, strawberry *Fragaria*, tabacco, oinions, sweet peppers			F/G	Late blight *Phytophthora infestans*		0.67 (0.06%)		until BBCH 59	1 to 6	7	67	150	0.1	0.1 to 0.6	7	
Spinach *Spinacia oleracea*																
Gardening Lettuce *Lactuca sativa*				Lettuce downy mildew water mould *Bremia lactucae*		0.1 to 0.2 (0.01 to 0.02%)		BBCH 17 to 19	1 to 7	7 to 10	10 to 200	1000	0.1 to 0.2	0.1 to 1.4		

Drip or injection (endotherapy)

Crop and/or situation (a)	Member State	Product Name	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (l)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season** (j)	Number min max (k)	Interval Between applications (min) (Days)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (*) (kg/ha)	kg a.i./ha min max (kg/ha) (l)		
Pear tree, *Pyrus communis*, apple tree *Malus sp.*	France & All Member states	Solution of essential oil of *Satureja Montana L.*	F	European canker *Nectria galligena*	EC (Emulsifiable concentrate)	1 (0.1%)	Injection or endotherapy	When large wounds are visible (all seasons)	1 to 2	21 to 30	0.1	20	0.02	0.02 to 0.04		Put the injector tip in the tree holes already existing and inject the dose directly in the carpophore of the fungus.
				Moniliose *Monilia fructigena*		20 (2%)	Drip	BBCH 60-79 Spring			2	30 to 150	0.6 to 3	0.6 to 6		15 to 75 mL of solution per tree is used (depending to circumference of tree) The drip consisting of a needle and a small tank is employed.
Apricot tree *Prunus armeniaca*, plum tree *Prunus domestica*, peach tree				Moniliose *Monilia laxa*								7.5 to 112.5	0.15 to 2.25	0.15 to 4.5		

Prunus persica																* The mix with essential oil must be used 24h after preparation
Date palm *Phoenix dactylifera*				Fusariose *Fusarium oxysporum*				Spring				1.5 to 22.5	0.03 to 0.5	0.03 to 1		
Chestnut *Castanea* apple tree *Malus pumila*, Grapvine *Vitis vinifera*				Root-rot *Phytophtora cinnamoni*		1 (0.1%)	Injection or endotherapy	BBCH 60-70			0.1	15 to 67	0.3 to 1.35	0.3 to 2.7		Put the injector tip in the tree holes already existing and inject the dose directly in the carpophore of the fungus The mix with essential oil must be used 24h after preparation
												20	0.02	0.02 to 0.04		
Pear tree *Pyrus communis*, apple tree *Malus sp.*, Hawthorn *Crataegus sp.*,				Fireblight *Erwinia amilorova*		2 (0.2%)	drip	Spring	1 to 2	21 to 30	2	30 to 150	0.06 to 0.3	0.06 to 0.6		15 to 75 mL of solution per tree is used (depending to circumference

rowan tree *Sorbus sp*																of tree) The drip consisting of a needle and a small tank is employed. ** The mix with essential oil must be used 24h after preparation

* e.g. The product can used for post-harvest application)*For uses where the column „Remarks. As above or other conditions to take into account
** The drip system is patented by E. Petiot
(a) For crops, the EU and Codex classification (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.* pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc…
(e) GCPF Codes – GIFAP Technical Monograph N° 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)
(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