European Commission

Combined Draft (Renewal) Assessment Report prepared according to Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008

THYMOL;
5-methyl-2-(propan-2-yl) phenol

Volume 3 – B.2 (AS)

Rapporteur Member State : Spain
Co-Rapporteur Member State : Greece

Version History

When	What
July 2022	Initial DRAR-RMS Spain
November 2022	DRAR after CoRMS and Applicant comments
February 2023	RAR updated after EFSA CoCh received on 24/01/2023

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS. Nevertheless, the views and conclusions of the RMS should always be clearly and transparently reported; the conclusions from the applicant should be included as an Applicant's statement for every single study reported at study level; and the RMS should justify the final assessment for each endpoint in all cases, indicating in a clear way the Applicant's assessment and the RMS reasons for supporting or not the view of the Applicant.

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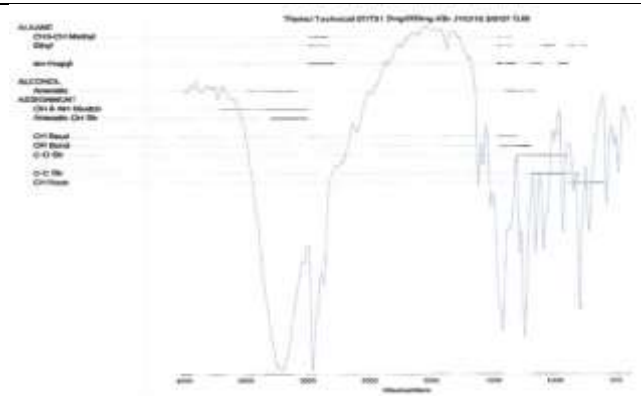
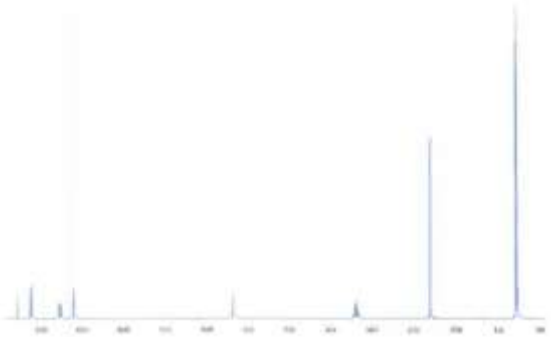
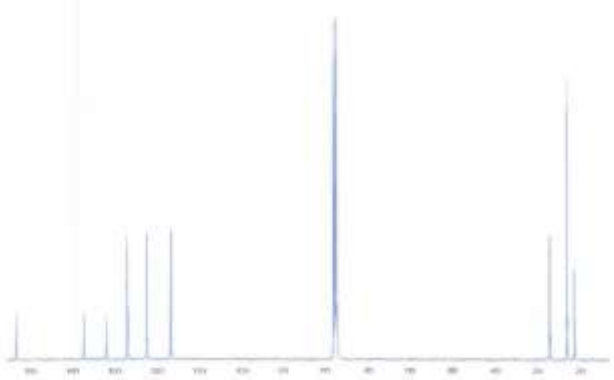
B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Thymol is a solid at ambient temperature, with a flash point of 105.5°C. It has a vapour pressure of 3.4 Pa and a Henry's Law Constant of 0.86 $Pa.m^3.mol^{-1}$ at 20°C. Thymol is relatively non soluble in water and reasonably soluble in organic solvents, with a pH-independent Log P_{ow} of around 3.4. Thymol is not flammable, not explosive and not oxidizing.

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. MELTING POINT AND BOILING POINT						
Melting, freezing or solidification point **B.2.1/01**	EEC A1 ASTM E537 (DSC method)	99.7% w/w Batch number 94747	Melting point: 48.75°C	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
Boiling point **B.2.1/02**	EEC A2 ASTM E537 (DSC method)	99.7% w/w Batch number 94747	Boiling point: 232.26°C	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
Decomposition / Sublimation temperature **B.2.1/03**	--	--	Not required. The melting point and the boiling point are submitted in the corresponding annex points.	**Acceptable**	--	--
B.2.2. VAPOUR PRESSURE, VOLATILITY						
Vapour pressure **B.2.2/01**	EEC A4, OECD 104	99.7% w/w Batch number 94747	Vapour pressure: 3.4 Pa @ 20°C	**Acceptable** Thymol is highly volatile.	Y	KCA 2.1/01 White G.A., 2007 Report number J16318

<table>
<tr><th>Test or Study Annex Point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td>Volatility (Henry's Law constant)
B.2.2/02</td><td>OECD 105
OECD 112</td><td>99.7% w/w
Batch number 94747</td><td>Henry's Law Constant: 0.86 Pa.m^3.mol^{-1} @ 20°C</td><td>Acceptable
The Henry´s Law constant was calculated within study from the solubility and vapour pressure data.</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007
Report number J16318</td></tr>
<tr><td colspan="7">B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)</td></tr>
<tr><td>Physical state and colour
Odour
B.2.3/01</td><td>Visual examination, Odour committee (smelling)</td><td>99.7% w/w
Batch number 94747</td><td>Fine, white, crystalline solid.
Strong phenolic/antiseptic, characteristic odour.</td><td>Acceptable</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007
Report number J16318</td></tr>
<tr><td colspan="7">B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY</td></tr>
<tr><td>Ultraviolet/visible (UV/VIS)
B.2.4/01</td><td>OECD 101
SOP/26</td><td>99.7% w/w
Batch number 94747</td><td>UV spectra is typical of thymol.
There are no maxima above 290 nm.
<table>
<tr><th>Solution</th><th>Concentration (mol/L)</th><th>Max. λ (nm)</th><th>Max. absorbance</th><th>Extinction coefficient ε</th></tr>
<tr><td>Neutral</td><td>0.0000240</td><td>196</td><td>1.1982</td><td>49925</td></tr>
<tr><td>Acidic</td><td>0.0000240</td><td>198</td><td>0.8909</td><td>37121</td></tr>
<tr><td>Alkaline</td><td>0.0000240</td><td>201</td><td>0.4487</td><td>18696</td></tr>
</table></td><td>Acceptable
The spectra were obtained in different pH conditions according to guideline.</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007
Report number J16318</td></tr>
<tr><td>Infrared (IR)
B.2.4/02</td><td>SOP/29
FTIR</td><td>99.7% w/w
Batch number 94747</td><td>IR spectrum is typical of Thymol.</td><td>Acceptable</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007
Report number J16318</td></tr>
</table>

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						
Nuclear magnetic resonance (NMR) **B.2.4/03**	SOP PRO/EQUIP/013, issue 9	99.7% w/w Batch number 94747	NMR spectrum is typical of Thymol. The proton scan and carbon scan NMR spectra recorded are consistent with the compound thymol. 	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						
Mass spectra (MS) **B.2.4/04**	SOP/78 GC-MS/MS	99.7% w/w Batch number 94747	MS spectrum is typical of Thymol. *m/z*= 135 (molecular ion and base peak) *m/z*= 150, 117, 107, 91 and 79	**Acceptable** The MS spectrum of the technical material was nearly identical to that of the analytical standard thymol with characteristic clusters of ions around.	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
Spectra for impurities **B.2.4/05**	--	--	Not applicable	Thymol does not have relevant impurities.	--	--
B.2.5. SOLUBILITY IN WATER						
Solubility in water **B.2.5/01**	EEC A6, OECD 105	99.7% w/w Batch number 94747	pH 4: 0.597 g/L pH 7: 0.596 g/L pH 9: 0.630 g/L All measured @ 20 ± 1°C	**Acceptable** The test covers the likely environmental range of pHs.	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
B.2.6. SOLUBILITY IN ORGANIC SOLVENTS						

<table>
<tr><th>Test or Study Annex Point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td>Solubility in organic solvents
B.2.6/01</td><td>CIPAC MT 181</td><td>99.7% w/w
Batch number 94747</td><td>n-Heptane: 200-250 g/L
p-Xylene: >250 g/L
1,2-Dichloroethane: >250 g/L
Methanol: >250 g/L
Acetone: >250 g/L
Ethyl acetate: >250 g/L

All measured @ 20 ± 1°C</td><td>Acceptable</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007
Report number J16318</td></tr>
<tr><td colspan="7">B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER</td></tr>
<tr><td>Partition coefficient n-octanol/water
B.2.7/01</td><td>EEC A8, OECD 107

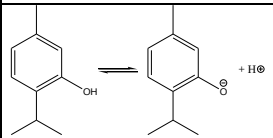
GC-FID</td><td>99.7% w/w
Batch number 94747</td><td>Log_{10} P = 3.97</td><td>Acceptable as additional information

The GC-FID method employed was adapted from method M622 (KCA 4.1.1/01). No full validation of the method is presented within KCA 2.1/01.</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007
Report number J16318</td></tr>
<tr><td>Partition coefficient n-octanol/water
B.2.7/02</td><td>EEC A8, OECD 107

HPLC-UV (validated method)</td><td>99.7% w/w
Batch number G161924</td><td><table><tr><td>pH</td><td>4</td><td>7</td><td>9</td></tr><tr><td>Log_{10} P_{ow}</td><td>3.43</td><td>3.44</td><td>3.41</td></tr></table>All measured @ 20 to 25 ± 1°C.
The pH has no impact on the octanol/water partition coefficient of thymol.</td><td>Acceptable upon study update
[Study Monitor signature is missing]

Unlikely to bioaccumulate.

The HPLC-UV method employed was validated against SANCO/3030/99 rev.5 . This test seems reliable to set and endpoint</td><td>Y</td><td>KCA 2.7/02
Lingott J., 2020
Report number S20-06644</td></tr>
<tr><td colspan="7">B.2.8. DISSOCIATION IN WATER</td></tr>
<tr><td>Dissociation constant
B.2.8/01</td><td>OECD 112</td><td>99.7% w/w
Batch number</td><td>pKa= 10.77</td><td>Acceptable</td><td>Y</td><td>KCA 2.1/01
White G.A., 2007</td></tr>
</table>

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		94747	 thymol	The datum is an average of results.The replicate tests were carried out at temperatures of between 21.8-22.8°C with no significant variations on the results.		Report number J16318
B.2.9. FLAMABILITY AND SHELF-HEATING						
Flammability **B.2.9/01**	EEC A10	99.7% w/w Batch number 94747	Material melted in contact with flame and ignited. However, material did not seem to burn in a true 'train'. Not flammable. (FP>60°C)	**Acceptable** The flash point relates to B.2.10/01.	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
Self heating **B.2.9/02**	EEC A15	99.7% w/w Batch number 94747	Autoflammability: >400°C	**Acceptable** Unlikely to self-ignite under normal storage conditions. Not self-heating.	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
B.2.10. FLASH POINT						
Flash point **B.2.10/01**	EEC A9 (closed cup)	99.7% w/w Batch number 94747	Flash point = 105.5°C No flammability classification required according to CLP criteria.	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
B.2.11. EXPLOSIVE PROPERTIES						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Explosive properties **B.2.11/01**	ASTM ES37-02 (DSC)	99.7% w/w Batch number 94747	Not explosive. No explosivity classification required according to CLP criteria.	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
B.2.12. SURFACE TENSION						
Surface tension **B.2.12/01**	EEC A5	99.7% w/w Batch number 94747	As a 0.54 g/L solution: 52.3 mN/m at 20°C 52.1 mN/m at 40°C The 0.54 g/L solution in water is considered surface active.	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
B.2.13. OXIDISING PROPERTIES						
Oxidizing properties **B.2.13/01**	EEC A17 and scientific reasoned case	99.7% w/w Batch number 94747	Not oxidising. The molecular structure of thymol does not contain any oxidising groups.	**Acceptable**	Y	KCA 2.1/01 White G.A., 2007 Report number J16318
B.2.14. OTHER STUDIES						
Relative density **B.2.14/01**	EEC A3 OECD 109 CIPAC MT 3.3.2	99.7% w/w Batch number 94747	Relative density D^{20}_4 = 1.012 at 20 ± 0.5°C	**Acceptable** Density: 1.012 kg/L	Y	KCA 2.1/01 White G.A., 2007 Report number J16318

B.2.15. REFERENCES RELIED ON

B.2.15.1. LITERATURE DATA

B.2.15.1.1 Literature search

Relevant MCA9 section of the dossier reviewed the literature data relating to the active substance thymol, as required by Article 8(5) of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market.

It has been written according to:

- EFSA (2011). Guidance of EFSA, Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009, EFSA Journal 2011;9(2):2092.

- AGES (2013). External scientific report, Case studies for the application of the Guidance of EFSA on Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009, using substances for which dossiers are submitted under Regulation (EU) No 1141/2010, EFSA supporting publication 2013:EN-511.

In this literature search, the aim was to find scientific peer-reviewed open literature on thymol dealing with toxicological and toxicokinetic studies, operator exposure, residues, fate and behaviour in the environment and ecotoxicological studies which were published between 1/1/2005 and 16/02/2021 for thymol.
To achieve this goal, a wide range of reference collections was consulted utilising the online various databases.

B.2.15.1.2. Search strategy

The following initial search strategy was used, in line with Section 5.2.2 of EFSA Journal 2011;9(2):2092:

- The search terms were defined, initially using terms related to the active substance, its metabolites and plant protection products containing the active substance, including synonyms.

- Specific search terms were then used relating to the specific data requirements in question (i.e. for toxicology, human exposure, residues, environmental fate and behaviour and ecotoxicology) to refine the search.

- The search of publications was conducted, using the two-stage approach outlined above. A list of titles, authors and dates were extracted. Any duplicate summary records were removed, before proceeding.

The remaining summary records were then assessed for relevance in a two-step process, in line with Section 5.3 of EFSA Journal 2011;9(2):2092:

- Firstly, a rapid assessment for relevance was conducted based on the titles and abstracts, to exclude summary records which were obviously irrelevant to the specific data requirements in question.

- Secondly, a detailed assessment of full-text documents was conducted to identify potentially relevant, irrelevant or relevant and reliable records that were not excluded in the first step.

All literature papers that were considered relevant to the risk assessment following this process are summarised in the corresponding MCA/MCP sections of this supplementary dossier, where an assessment of their reliability is also presented in line with Section 5.4 of EFSA Journal 2011;9(2):2092.

B.2.15.1.3. Date of the literature search

The literature search was conducted between 2nd July 2020 and 16/17 February 2021.

B.2.15.1.4. Time period covered in the literature search

The search identified scientific peer-reviewed open literature published in the last 15 years (from 1/1/2005 to 16/02/2021) for thymol.

B.2.15.1.5. Bibliographic databases used in the literature review

In line with Section 5.2.1 of EFSA Journal 2011;9(2):2092, a number of different sources were used in the literature search with the aim to locate all relevant scientific peer-reviewed open literature. The reference collections searched were AGRICOLA, AGRIS (FAO), PASCAL, PubMed (MEDLINE) inc. TOXNET, Science Direct, Springer, and Wiley. All sources and the rationale for their inclusion in the search are presented in the table below.

Table B.2.15-1: Bibliographic databases used in the literature search

Database	Description/Rationale for Inclusion
1. AGRICOLA	Coverage of the database includes agricultural economics and rural sociology, agricultural production, animal sciences, chemistry, entomology, food and human nutrition, forestry, natural resources, pesticides, plant science, soils and fertilizers, and water resources. More than 6.7 million records (09/2019). 1970-present.
2. AGRIS (FAO)	AGRIS is one of the most comprehensive search engines in food and agricultural scientific literature providing free access to millions of bibliographic records in 90 different languages. Up to hundreds of organisations worldwide contribute to knowledge and data to the AGRIS platform, resulting in a multilingual bibliographic collection of food and agricultural scientific research with special attention to scientific information produced in the global south. Therefore, AGRIS is used by whoever is inclined to find literature on any of FAO's areas of interest.
3. PASCAL	The site is an archive of the PASCAL and FRANCIS bibliographic databases in exact, human and social sciences, produced by the Inist-CNRS from 1972 to 2015. It provides access to more than 20 millions references (articles, patents, maps, conferences, books, reports and thesis) in exact sciences and technology, in biological and medical sciences, in art, archaeology, economics, ethnology, geography, history of science and technology, literature, linguistics, administrative and legal sciences, education and religion sciences.
4. PubMed MEDLINE (including TOXNET)	MEDLINE contains information on every area of medicine. More than 30 million records (08/2019). 1946-present.
5. Science Direct	ScienceDirect provides access to more than 16 million articles, 2,500 journals, 370 full open access journals, 39,000 books and 330,000 topic pages to help researchers discover more insights, achieve more breakthroughs and move their research forward.
6. Springer	Springer is a leading global scientific, technical and medical portfolio, providing researchers in academia, scientific institutions and corporate R&D departments with quality content through innovative information, products and services. It handles more than 2,900 journals and 300,000 book.
7. Wiley	Wiley is one of the largest and most authoritative collections of online journals, books, and research resources, covering life, health, social, and physical sciences.

B.2.15.1.6. Input parameters (search terms) for the literature search

Any documents relating to the essential oils, their synonyms and other common names were collected. The reference collections were queried by name e.g. "thymol" in addition to common variants such as thymic acid, and "thyme campher". Where the number of records for, say, thymol alone exceeded individual reference collection download limits additional specific topics of interest, ecotoxicity, fate, residues, etc., were included. The tables below present the general search terms used:

Table B.2.15-2: List search terms used to identify all literature related to the active substance (thymol), its metabolites and plant protection products containing the active substance

Common name	Thymol Thyme camphor Thymic acid Cymophenol, alpha- m-Thymol IPMP Isopropyl cresol Cymophenol, alpha- phenol
Chemical name (IUPAC and CA)	5-methyl-2-propan-2-ylphenol 2-Isopropyl-5-methylphenol 5-Methyl-2-isopropylphenol 1-Hydroxy-5-methyl-2-isopropylbenzene 1-Methyl-3-hydroxy-4-isopropylbenzene 2-Hydroxy-1-isopropyl-4-methylbenzene 2-Isopropyl-5-methylphenol 3-Hydroxy-1-methyl-4-isopropylbenzene 3-Hydroxy-p-cymene 3-Methyl-6-isopropylphenol 3-p-Cymenol 5-Methyl-2-(1-methylethyl)phenol 5-Methyl-2-isopropyl-1-phenol Methyl-2-isopropylphenol 6-Isopropyl-3-methylphenol 6-Isopropyl-m-cresol 6-Isopropyl-p-cresol Phenol, 5-methyl-2-(1-methylethyl)- Phenol, 2-isopropyl-5-methyl-
Metabolite(s)	-
Product name	Mevalone, Cedroz, Andromeda, 3Logym ES-00108, Trigemol, Cagenoleta, Eugeti
CAS No.	89-83-8
EC No.	201-944-8

B.2.15.1.7. Search results

The total numbers of records (before removing duplicates) for the search are summarised in the table below. The full results of the search (spreadsheets) are provided at KCA 9.3/01.
The peer-reviewed literature search strategy highlighted for first search (done in 2020), 33 715 documents, for second search (done in 2021), 1 514 documents, total 35 229 documents of potential interest for thymol to this review before the removal of duplicates occurring as a result of searching the individual reference collections separately.

Table B.2.15-3: Numbers of records (before removing duplicates) for the search (based on search terms according to Table B.2.15-2)

Databases (through online STN)	**Number of hits Thymol First search**	**Number of hits Thymol Second search**	**Number of hits Thymol Total**
1. AGRICOLA	-	88	88
2. AGRIS (FAO)	190	14	204
3. PASCAL	-	-	-
4. PubMed MEDLINE (including TOXNET)	17 870	223	18 093
5. Science Direct	7 424	219	7 643
6. Springer	4 701	575	5 276
7. Wiley	3 530	395	3 925
Total number of documents retrieved (with duplicates) (global search results related to the active substance, its metabolites and plant protection products containing the active substance)	**33 715**	**1 514**	**35 229**

To identify which of these records mentioned the aspects of interest to this particular project a text mining application was built and applied to each document in turn and only those which specifically mentioned, for example fate and behavior or the specified ecotox terms together with an essential oil or its common variants, were identified as a positive result.
The text mining application comprises a number of different steps each performing a different function in the application and in general terms the approach taken was to Tokenise (identify individual words and features) and Sentence split the documents; use the Gazetteer lists to identify any important key words and phrases such as sediment dwelling organisms; identify the Title and Abstract part of the document; look within the Title and Abstract for patterns matching the natural language expressions for, say, the ecotoxicity of thymol, an example being "Acaricidal activities of *Santolina africana* and *Hertia cheirifolia* essential oils against the two-spotted spider mite (*Tetranychus urticae*)."; and index the results.
After removing duplicates and text mining process, the total number of hits potentially relevant is presented below:

Table B.2.15-4: Number of documents identified as potentially relevant after text mining and removal of duplicates

All databases	**Number of hits* Thymol**
Mammalian Toxicity	494
Residues	303
Environmental fate and behaviour	510
Ecotox	1120

*Total number of documents retrieved after removal of duplicates/triplicates (using general plus section specific terms).

B.2.15.1.8. Study selection

The remaining summary records were assessed for relevance in a two-step process, in line with Section 5.3 of EFSA Journal 2011;9(2):2092:

- Firstly, a rapid assessment for relevance was conducted based on the titles and abstracts, to exclude summary records which were considered irrelevant and the justification was recorded.

- Secondly, a detailed assessment relevance and reliability of full-text documents was conducted for any remaining summary records that were not excluded in the first step.

All literature papers that were considered relevant to the risk assessment following this two-step process are summarised in the corresponding MCA/MCP sections of this supplementary dossier, where an assessment of their reliability is also presented in line with Section 5.4 of EFSA Journal 2011;9(2):2092.

B.2.15.1.8.1 Rapid assessment
The total number of publications excluded after rapid assessment for relevance and the number of publications for which a detailed assessment of the full-text was required are summarised in the table below. Full details of the rapid assessment are presented in spreadsheet KCA 9.4/01 for thymol

Table B.2.15-5: Numbers of publications excluded/identified after rapid assessment for relevance for thymol

Study selection process	Thymol			
	Toxicology (including human exposure)	Residues	Environmental fate and behaviour	Ecotoxicology
Number of publications excluded after rapid assessment for relevance (non-relevant, excluded literature)	481	284	507	983
Number of publications for which detailed assessment of full-text required after rapid assessment for relevance	13	19	3	137

B.2.15.1.8.2 Detailed assessment

The total number of publications excluded and the final number of relevant papers identified after detailed assessment of full-texts for relevance are summarised in the tables below. Full details of the detailed assessment are presented in spreadsheet KCA 9.4/01 for thymol.

Table B.2.15-6: Numbers of publications excluded/identified after detailed assessment for relevance for thymol

Study selection process	Thymol			
	Toxicology (including human exposure)	Residues	Environmental fate and behaviour	Ecotoxicology
Number of publications excluded from further consideration after detailed assessment for relevance (non-relevant, excluded literature)	3	9	0	93
Number of publications considered relevant following the two-step process (i.e. after detailed assessment of full-text)	**10**	**10**	**3**	**44***

* Includes 41 papers, plus 3 papers for which full-text was not available. In absence of the full-text, these 3 papers are considered relevant and the available abstract has been provided as a summary (but cannot be assessed for reliability).

B.2.15.1.9. Conclusion

In this literature search for the active substance thymol, 35 229 references were identified and evaluated for their potential relevance for data requirements “toxicological and toxicokinetic studies, human exposure, residues, fate and behaviour in the environment and ecotoxicological studies”.
After rapid and detailed assessments for relevance, the following publications were considered to be relevant:

	Number of publications considered to be relevant Thymol From 01/01/2005 to 16/02/2021
Toxicology, including human exposure	10
Residues	10

Environmental fate	3
Ecotoxicology	44*

* Includes 41 papers, plus 3 papers for which full-text was not available. In absence of the full-text, these 3 papers are considered relevant and the available abstract has been provided as a summary (but cannot be assessed for reliability).

All relevant and reliable publications identified following the detailed assessment are summarised in the corresponding MCA/MCP sections of this supplementary dossier, where an assessment of their reliability is also presented in line with Section 5.4 of EFSA Journal 2011;9(2):2092

There are not literature references related to thymol physico-chemical properties.

B.2.15.2. REFERENCE LIST

Data Point	**Author(s)**	**Year**	**Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously used[1] Y/N If yes, for which data point?**
KCA 2.1/01 **B.2.1/01** **B.2.1/02**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.1
KCA 2.1/01 **B.2.2/01** **B.2.2/02**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.3
KCA 2.1/01 **B.2.3/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.4
KCA 2.1/01 **B.2.4/01** **B.2.4/02** **B.2.4/03** **B.2.4/04**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.5

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCA 2.1/01 **B.2.5/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.6
KCA 2.1/01 **B.2.6/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.7
KCA 2.1/01 **B.2.7/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.8
KCA 2.7/02 **B.2.7/02**	Lingott J.	2020	Partition Coefficient of Thymol (Shake Flask Method) Report number S20-06644 Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Study not previously submitted	Eden Research plc	N
KCA 2.1/01 **B.2.8/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.9
KCA 2.1/01 **B.2.9/01** **B.2.9/02**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.11

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
			G.C. Laboratories Ltd GLP Unpublished					
KCA 2.1/01 **B.2.10/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.12
KCA 2.1/01 **B.2.11/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.13
KCA 2.1/01 **B.2.12/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.14
KCA 2.1/01 **B.2.13/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.15
KCA 2.1/01 **B.2.14/01**	White G.A.	2007	Thymol Technical Material Physical/Chemical Tests Report n° J16318 G.C. Laboratories Ltd GLP Unpublished	N	N	-	Eden Research plc	Y In DAR (2011) IIA 2.2

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.

[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013
[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).