Safety and efficacy of a feed additive consisting of an essential oil derived from the aerial parts of Mentha spicata L. (spearmint oil) for use in all animal species (FEFANA asbl)

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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of an essential oil derived from the aerial parts of *Mentha spicata* L. (spearmint oil) for use in all animal species (FEFANA asbl)

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of an essential oil from the aerial parts of *Mentha spicata* L. (spearmint oil) when used as a sensory additive in feed and in water for drinking for all animal species. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the additive under assessment is considered safe up to the maximum use level of 10 mg/kg complete feed for all animal species. The FEEDAP Panel considered that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed. The use of the additive in animal feed under the proposed conditions of use is safe for the consumer and the environment. Regarding user safety, the essential oil under assessment should be considered as an irritant to skin and eyes and as a dermal and respiratory sensitiser. Exposure of users by any route is considered a risk. Since spearmint oil is recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy was considered necessary.

KEYWORDS

d-limonene, efficacy, flavouring compounds, *l*-carvone, *Mentha spicata* L., safety, sensory additives, spearmint oil

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person-seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7. In particular, Article 10(2) of that Regulation specifies that, for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, within a maximum of 7 years after the entry into force of this Regulation.

The European Commission received a request from the Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)[2] for authorisation/re-evaluation of 41 additives (king of bitter extract, thyme-leaved gratiola tincture, devils claw extract, devils claw tincture, lavender oil, lavender tincture, spike lavender oil, melissa oil, balm leaves extract, mentha arvensis/corn mint oil, pennyroyal oil, spearmint oil, peppermint oil, peppermint tincture, basil oil, basil tincture, olive extract, marjoram oil, oregano oil, oregano tincture, patchouli oil, rosemary oil, rosemary oleoresin, rosemary extract, rosemary tincture, Spanish sage oil, sage oil, sage tincture, clary sage oil, savoury summer oil, savoury summer tincture, Pau darco tincture, thymus origanum oil, thyme oil, thyme oleoresin, thyme extract, thyme tincture, lilac chaste tree extract, lilac chaste tree tincture, Spanish marjoram oil and wild thyme tincture) belonging to botanically defined group (BDG) 01 – Lamiales, when used as a feed additive for all animal species (category: sensory additives; functional group: flavouring compounds). During the assessment, the applicant withdrew the applications for 12 additives.[3] These additives were deleted from the register of feed additives.[4] In addition, during the course of the assessment, the application was split and the present opinion covers only one out of the remaining 29 additives under application: spearmint oil from *Mentha spicata* L. for use in all animal species.

The remaining 28 additives belonging to the botanically defined group (BDG) 01 – Lamiales under application are assessed in separate opinions.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 1 June 2011.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of spearmint oil from *M. spicata*, when used under the proposed conditions of use (see **Section 3.3.3**).

1.2 | Additional information

Spearmint oil from *Mentha spicata* L. is currently authorised as a feed additive according to the entry in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 (2b natural products – botanically defined). It has not been assessed as a feed additive in the EU.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[5] in support of the authorisation request for the use of spearmint oil from *M. spicata* as a feed additive. The dossier was received on 26 June 2025 and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2025-00405.[6]

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2]On 13/3/2013, EFSA was informed by the applicant that the applicant company changed to FEFANA asbl, Avenue Louise 130 A, Box 1, 1050 Brussels, Belgium.
[3]Thyme leaves gratiola tincture, spike lavender oil, melissa oil, pennyroyal oil, basil oil and savoury summer oil (27 February 2019); Spanish majoram oil (28 September 2023); lilac chastetree extract and savoury summer tincture (8 July 2024); devil's claw extract (wb), balm leaves extract (sb), olive extract (sb) (16 December 2024).
[4]Register of feed additives, Annex II, withdrawn by OJ L 162, 10.05.2021, p. 5.
[5]Dossier reference: FAD-2010-0137.
[6]The original application EFSA-Q-2010-0137 was split on 26/06/2025 and a new EFSA-Q-2025-00405 was generated.

Many of the components of the essential oil under assessment have already been evaluated by the FEEDAP Panel as chemically defined flavourings (CDGs). The applicant submitted a written agreement to reuse the data submitted for the assessment of chemically defined flavourings (dossiers, publications and unpublished reports) for the risk assessment of preparations belonging to BDG 01, including the current one under assessment.[7]

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the phytochemical markers in the additive. During the assessment, upon request of EFSA, the EURL issued two partial reports.[8] The additive under assessment is included in the second partial report. In particular, the EURL recommended a method based on gas chromatography with flame ionisation detection (GC-FID) for the quantification of the phytochemical marker *carvone* in *spearmint oil*.[9]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and efficacy of spearmint oil from *M. spicata* is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA Scientific Committee, 2009), Compendium of botanicals,[11] Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024), Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019a), Statement on the genotoxicity assessment of chemical mixtures (EFSA Scientific Committee, 2019b), Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Scientific Committee, 2019c).

3 | ASSESSMENT

The additive under assessment, spearmint oil, is an essential oil obtained from the aerial parts of the flowering plant of *Mentha spicata* L. and is intended for use as a sensory additive (functional group: flavouring compounds) in feed and in water for drinking for all animal species.

3.1 | Origin and extraction

Mentha spicata L. is a perennial herbaceous plant belonging to the family Lamiaceae. It has a widespread distribution in temperate regions, with a native range from Europe to China and subsequent introductions into North and South America. The species has two recognised intraspecifics, *Mentha spicata* subsp. *spicata* being the more common with a distribution which mirrors that of the species as a whole and *Mentha spicata* subsp. *condensata* (Briq.) Greuter & Burdet with a distribution restricted to parts of the eastern Mediterranean. Its common name spearmint derives from the spear-like shape of its leaves. It is also referred to as the garden mint, the common mint or lamb mint. *M. spicata* is typical of plants in the mint family having creeping rhizomes from which develop upright stems (up to 100 cm), carrying bright green leaves in opposite pairs. It produces pale purple flowers in terminal spikes in season. It is widely grown as a culinary herb and as an ornamental plant.

The additive is extracted from the fresh or dried aerial parts of *Mentha spicata* L. at flowering by steam distillation. The volatile constituents are condensed and then separated from the aqueous phase by decantation. The oil may also be subject to rectification (fractional distillation) and the fractions obtained are mixed with the essential oil to reach the specified profile. In the current assessment, the applicant submitted analytical data on spearmint oil obtained by either (i) steam distillation or (ii) fractional distillation (rectification) and subsequent blending to achieve the intended specifications.

[7]Technical dossier/Supplementary information August 2024/Letter dated 27/8/2024.

[8]Additives included in the first partial report: Spanish sage oil, peppermint oil, thymus origanum oil, patchouli oil, clary sage oil, lavender oil and sage oil; additives included in the second partial report: cornmint oil, spearmint oil, thyme oil, rosemary oil, marjoram oil, rosemary tincture, basil tincture, lavender tincture, peppermint tincture, sage tincture and wild thyme tincture.

[9]Evaluation report received on 18/06/2025 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2010-0137_en.

[10]Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[11]Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals.

3.2 | Uses other than feed flavouring

There is no specific EU authorisation for any *M. spicata* preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008[12] flavouring preparations produced from food, may be used without an evaluation and approval as long as 'they do not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer, and their use does not mislead the consumer.'

3.3 | Characterisation

3.3.1 | Characterisation of spearmint oil

The essential oil is obtained from the aerial parts of *Mentha spicata* L. sourced from China and India. It is a clear, pale-yellow liquid with a typical note of spearmint. Spearmint oil is identified with the single Chemical Abstracts Service (CAS) number 8008-79-5, the European Community (EC) number 283-656-2,[13] the Flavor Extract Manufacturers Association (FEMA) number 3032 and the Council of Europe (CoE) number 285.

In six batches of the additive, the refractive index (20°C) fell within the range 1.487–1.493. In three batches, the density (20°C) ranged between 918 and 921 kg/m^3, and the optical rotation (20°C) ranged between −56.79° and − 53.48°.[14]

The applicant provided a full analysis of six batches of spearmint oil (three obtained by steam distillation and three by fractional distillation) using gas chromatography–mass spectrometry (GC–MS)[15] and expressed as a percentage of gas chromatographic peak area (% GC area). Table 1 summarises the analytical results for the essential oils obtained by different manufacturing processes (steam distillation or fractional distillation). The oil obtained by fractional distillation showed an enrichment in *l*-carvone (+26%) and other carvyl derivatives (*trans*-dihydrocarvyl acetate and dihydrocarveol) compared to the oil obtained by steam distillation. The increase in the % of *l*-carvone (76.5% vs. 49.5%) is balanced by the reduction in the % of other terpenes, e.g. *d*-limonene (4.5% vs. 19.3%), β-bourbonene (0.07% vs. 2.02%), myrcene (0.04% vs. 2.52%), 1,8-cineole (0.08% vs. 1.72%), β-caryophyllene (0.18% vs. 1.39%), β-pinene (0.05% vs. 1.39%) and α-pinene (0.05% vs. 1.37%). The FEEDAP Panel noted that fractional distillation and subsequent blending do not result in an increase in the content of substances of concern in spearmint oil.

TABLE 1 Comparison of the constituents of spearmint oil obtained by steam distillation (three batches) and fractional distillation (three batches) analysed by gas chromatography–mass spectrometry (GC-MS). The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%. Constituents accounting for > 0.2% of the % GC area are shown in the table.

Constituent			% GC area			
			Steam distillation		Fractional distillation	
EU register name	CAS no	FLAVIS no	Mean	Range	Mean	Range
l-Carvone[1]	6485-40-1	07.147	49.46	48.45–50.78	76.47	76.05–76.75
d-Limonene[2]	5989-27-5	01.045	19.26	16.70–20.78	4.52	4.40–4.60
cis-Dihydrocarvone	3792-53-8	–	2.49	1.91–3.44	2.78	2.65–2.86
β-Bourbonene	5208-59-3	01.024	2.02	2.01–2.03	0.07	0.06–0.08
trans-Dihydrocarvyl acetate	57287-13-5	–	0.70	0.27–1.50	3.69	3.68–3.71
Dihydrocarveol	619-01-2	02.061	–	–	2.78	2.65–2.86
Menthol[3]	89-78-1	02.015	2.28	1.83–2.54	2.58	2.43–2.86
Myrcene	123-35-3	01.008	2.52	2.06–3.00	0.04	0.02–0.05
1,8-Cineole	470-82-6	03.001	1.72	1.68–1.74	0.08	0.07–0.08
Menthone[4]	89-80-5	07.176	0.77	0.58–0.88	1.51	1.48–1.54
β-Caryophyllene	87-44-5	01.007	1.39	1.24–1.49	0.18	0.15–0.21

(Continues)

[12]Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Regulation (EC) No 1601/91 of the Council, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34.

[13]The following entries were found at https://echa.europa.eu/home: 'Spearmint oil' EC 937–710-3; 'Spearmint oil'. EC 682–564-3, CAS 84896–51-5. 'Spearmint, ext.' (defined as extracts from *Mentha spicata*, Labiatae. including essential oils): EC 283–656-2; CAS 84696–51-5. 'Essential oil of Spearmint obtained from the aerial part of *Mentha spicata* and/or *Mentha cardiaca* (Lamiaceae) obtained by distillation' EC 946–253-9. 'Spearmint oil natural' EC 932–413-5; 'Spearmint oil, Mentha spicata' EC 932-417-7.

[14]Technical dossier/Supplementary information December 2024/Annex_II_SIn_reply_spearmint_oil_CoAs_chrom.

[15]Technical dossier/Supplementary information December 2024/Annex_II_SIn_reply_spearmint_oil_CoAs_chrom.

TABLE 1 (Continued)

Constituent			% GC area			
			Steam distillation		Fractional distillation	
EU register name	CAS no	FLAVIS no	Mean	Range	Mean	Range
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	1.39	1.29–1.44	0.05	0.03–0.09
α-Pinene (pin-2(3)-ene)	80-56-8	01.004	1.37	1.26–1.45	0.05	0.03–0.07
4-Terpinenol	562-74-3	02.072	0.87	0.81–0.95	0.11	0.11–0.12
Sabinene (4(10)-thujene)	3387-41-5	01.059	0.86	0.80–0.92	0.02	0.02–0.03
Germacra-1(10),4(14),5-triene	23986-74-5	01.042	0.81	0.39–1.05	–	–
trans-Dihydrocarvone	5948-04-9	–	0.30	0.24–0.41	0.76	0.67–0.80
trans-β-Farnesene	18794-84-8	–	0.70	0.63–0.80	–	–
Neodihydrocarveol	18675-34-8	–	0.62	0.50–0.78	–	–
d,l-Isomenthone[5]	491-07-6	07.078	0.61	0.51–0.68	0.60	0.54–0.70
trans-Carveol	1197-07-5	-	0.51	0.46–0.60	0.58	0.57–0.59
Octan-3-ol	589-98-0	02.098	0.57	0.54–0.60	0.05	0.04–0.09
p-Menth-1-en-3-one	89-81-6	07.175	0.50	0.34–0.59	0.13	0.10–0.18
(1R,5R)-Carvyl acetate	1205-42-1	09.845	0.50	0.31–0.85	–	–
p-Cymene (1-isopropyl-4-methylbenzene)	99-87-6	01.002	0.45	0.30–0.68	0.10	0.10–0.12
α-Terpineol	98-55-5	02.014	0.44	0.32–0.56	0.10	0.08–0.12
cis-Carveol	1197-06-4	-	0.34	0.32–0.37	0.42	0.38–0.45
Menthyl acetate[6]	16409-45-3	09.016	0.42	0.38–0.44	0.26	0.25–0.27
trans-Sabinene hydrate	17699-16-0	–	0.39	0.30–0.49	0.01	0.01–0.01
Isomenthol	490-99-3	–	–	–	0.31	0.13–0.40
3-Methyl-2(pent-2-enyl)cyclopent-2-en-1-one	488-10-8	07.094	0.23	0.20–0.26	–	–
3-Octyl acetate	4864-61-3	09.254	0.22	0.13–0.41	–	–
β-Elemene	33880-83-0	–	0.21	0.19–0.24	–	–
Total			94.9[7]	94.2–95.4[8]	96.0[7]	94.2–98.4[8]

Abbreviations: CAS no. Chemical Abstracts Service number; EU, European Union; FLAVIS No, EU Flavour Information System number.

[1]Carvone [07.012]: stereochemistry not given; however, *l*-carvone occurs in flowering tops of *Mentha spicata* L. (EFSA Scientific Committee, 2014; Tisserand & Young, 2014).

[2]Limonene [01.001]: Stereochemistry not given; however, considering that the naturally occurring limonene is typically *d*-limonene, it is assumed that this form also occurs in spearmint oil.

[3]Menthol [02.105]: The stereochemistry is not specified, but the analytical data provided refer to (–)-menthol (= *l*-menthol) which is the natural one (EFSA FEEDAP Panel, 2016b). The same FLAVIS number [02.015] can be used to identify the racemate *d,l*-menthol and its isomeric forms (EFSA FEEDAP Panel, 2020).

[4]*trans*-Menthone, [07.176]: two diastereoisomers (+)-menthone and (–)-menthone in *trans*-configuration [07.176]. Referred in the opinion to as menthone.

[5]*d,l*-Isomenthone [07.078]: two diastereoisomers (+)-isomenthone and (–)-isomenthone in *cis*-configuration.

[6]Stereochemistry not specified.

[7]The value given for the total (mean) is the mean of the sum of the constituents in the individual batches analysed.

[8]The values given for the total (range) are the lowest and the highest values of the sum of the constituents in the individual batches analysed.

When considering the overall data set, up to 75 peaks were detected and identified in the chromatograms, accounting on average for 99.1% (98.2%–99.7%) of the GC area. The 33 compounds detected at individual levels of > 0.2% and listed in Table 1 together account on average for 96.6% (range 94.2%–98.4%) of the GC area. The remaining 40 compounds (ranging between 0.2% and 0.008%) and accounting for 2.5% of the GC area are listed in the footnote.[16] Based on the available data, spearmint oil is considered a fully characterised mixture, as defined by the EFSA Scientific Committee (2019).

The product specifications used by the applicant are based on the standard developed by the International Organisation for Standardisation (ISO) 3033–1:2005 ('Oil of spearmint') Part 1: Native type [Mentha spicata L.] and ISO 3033-3:2005 ('Oil of spearmint'), Part 3: Indian type [Mentha spicata L.] ('redistilled oil') adapted to reflect the concentrations of selected volatile components in spearmint oils obtained by either steam distillation or fractional distillation. Four components contribute to the specifications as shown in Table 2, with carvone selected as the phytochemical marker. Analysis of six batches of the additive (three obtained by steam distillation and three by fractional distillation) showed compliance with the specifications when analysed by GC-FID and expressed as a percentage of gas chromatographic peak area (% GC area).

[16]Additional constituents: constituents ($n = 30$) between < 0.2% and ≥0.05%: viridiflorol, β-cubebene, γ-muurolene, β-caryophyllene epoxide, γ-terpinene, α-terpinene, pseudolimonene, 2,5-diethyltetrahydrofuran, δ-terpineol, 4(15),10(14)-cadinadiene, δ-cadinene, terpinolene, isopulegol, carvone-5,6-oxide, *cis*-3,7-dimethyl-1,3,6-octatriene (*cis*-β-ocimene), α-copaene, *trans*-1-methyl-4-(1-methylvinyl)cyclohex-2-en-1-ol, decan-1-ol, 3,7,10-humulatriene, α-thujene, linalool, β-copaene, *cis-p*-2,8-menthadien-1-ol, *trans*-limonene epoxide, octyl acetate, octan-3-one, octan-1-ol, isopiperitenol, camphene, 1-isopropenyl-4-methylbenzene; constituents ($n = 10$) between < 0.05% and ≥ 0.008%: neoisomenthol, *trans*-3,7-dimethyl-1,3,6-octatriene (*trans*-β-ocimene), octanal, eugenol, *cis*-sabinene hydrate, *p*-mentha-1,4(8)-dien-3-one, hex-3*(cis)*-en-1-ol, bicyclosesquiphellandrene, *p*-1-menthene, neoisomenthyl acetate.

TABLE 2 Constituents of spearmint oil as defined by specifications, and batch to batch variation based on the analysis of six batches by gas chromatography with flame ionisation detector (GC-FID). The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%.

Constituent			% GC area		
EU register name	**CAS no**	**FLAVIS no**	**Specification[1]**	**Mean**	**Range**
l-Carvone[2]	6485-40-1	07.147	55–87	68.5	55.4–81.1
d-Limonene[3]	5989-27-5	01.045	2–25	12.3	4.19–22.1
cis-Dihydrocarvone	3792-53-8	–	< 5.5	3.14	1.31–4.7
β-Bourbonene	5208-59-3	01.024	< 2.0	0.65	0.05–1.35

Abbreviations: CAS no, Chemical Abstracts Service number; EU, European Union; FLAVIS no, EU Flavour Information System numbers.

[1]Specification defined based on GC-FID analysis.

[2]Carvone: stereochemistry not given; however, *(l)*-carvone occurs in flowering tops of *Mentha spicata* L. (EFSA Scientific Committee, 2014; Tisserand & Young, 2014).

[3]Limonene: stereochemistry not given; however, considering that the naturally occurring limonene is typically *d*-limonene, it is assumed that this form also occurs in spearmint oil (Tisserand & Young, 2014).

The EFSA Compendium of botanicals[17] reports as substances of potential concern for human and animal health the occurrence of (+)-pulegone (72.1%), 1,8-cineole (1%–7%), carvone (59%–77%), *d,l*-isomenthone (2.6%–32%), dihydrocarvone (1%–4%), menthone (14%–15.6%), myrcene (2.1%) in the essential oil from the aerial parts of *M. spicata*. One publication (Cook et al., 2007) reported the presence of 1,8-cineole (10.8%–37.9%) and the 1,2-epoxy-*p*-menthane derivatives, namely *trans*-piperitone oxide (1.4%–32.5%) and piperitenone oxide (21.8%–27.5%) as the major components of essential oils originating from different locations of Zakynthos Island (Greece). As the composition of these oils differs substantially from that of the additive under evaluation, this publication was not further considered.

The applicant carried out an extensive literature search to identify data related to the chemical composition of ***M. spicata*** and its botanical preparations and the possible presence of substances of concern.[18] Four cumulative databases (LIVIVO, NCBI, OVID and ToxInfo) were searched. The keywords used covered different aspects of safety, and the inclusion and exclusion criteria were provided by the applicant. The literature search (no time limits specified) retrieved 23 references investigating the composition of spearmint oil. The results of the literature search confirmed the information in the EFSA Compendium. In addition, three studies reported the presence of estragole, α-thujone, β-thujone and/or perillaldehyde in *M. spicata* essential oils from Iraq or Algeria (Al-Ibrahemi et al., 2023; Amel et al., 2022; Jaber & Khashan, 2023). As the composition of the analysed oils differs substantially from that under evaluation, these publications were not considered relevant for the current assessment.

3.3.1.1 | *Impurities*

The applicant referred to the 'periodic testing' of some representative flavourings premixtures for mercury, cadmium, lead, arsenic, fluoride, dioxins and polychlorinated biphenyls (PCBs), organo-chlorine pesticides, organo-phosphorous pesticides, aflatoxins (B1, B2, G1, G2) and ochratoxin A. However, no data were provided on the presence of these impurities.

3.3.2 | Shelf-life

The typical shelf-life of spearmint oil is stated to be at least 12 months, when stored in tightly closed containers under standard conditions (in a cool, dry place protected from light).[19] However, no data supporting this statement were provided.

3.3.3 | Conditions of use

Spearmint oil is intended to be added to feed and water for drinking for all animal species without a withdrawal period. The maximum use level in complete feed proposed for all animal species and categories is listed in Table 3. No use level has been proposed for the use of the additive in water for drinking.

[17]Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals, accessed on 11 June 2025.

[18]Technical dossier/Supplementary information December 2024/Literature search_spearmint_oil.

[19]Technical dossier/Section II.

TABLE 3 Maximum proposed use levels of spearmint oil in complete feed.

Animal category	Maximum proposed use level (mg/kg complete feed)
Chickens for fattening	25
Laying hens	25
Turkeys for fattening	25
Piglets	50
Pigs for fattening	50
Sows	50
Veal calves (milk replacers)	25
Cattle for fattening	100
Dairy cows	100
Sheep/goats	100
Horses	100
Rabbits	25
Salmon and other fin fish	25
Dogs	25
Cats	25
Ornamental fish	25
Other species	25

3.4 | Safety

No studies to support the safety for target animals, consumers and users were performed with the additive under assessment.

Forty-four of the individual components of the essential oil, accounting on average for 90.3% of the GC area, have already been assessed as chemically defined flavourings for use in feed and food by the FEEDAP Panel, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), the EFSA Panel on Food Additives and Flavourings (FAF) and/or by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The flavouring compounds together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000[20] and the corresponding EFSA opinion are listed in Table **4**.

TABLE 4 Flavouring components of spearmint oil already assessed by EFSA and/or by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as chemically defined flavourings, grouped according to the chemical group (CG) as defined in Commission Regulation (EC) No 1565/2000, with an indication of the EU Flavour Information System (FLAVIS) number and the corresponding EFSA/JECFA opinion.

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA/JECFA opinion,* year
01	Straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes	Octan-1-ol	02.006	2013
		Decan-1-ol	02.024	
		Octanal	05.09	
		Octyl acetate	09.007	
04	Non-conjugated and accumulated unsaturated straight-chain and branched-chain aliphatic primary alcohols, aldehydes, acids, acetals and esters	Hex-3(*cis*)-en-1-ol	02.056	2016a
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	Octan-3-ol	02.098	2015a
		Octan-3-one	07.062	2015a, 2023b
		Isopulegol	02.067	2020a
		3-Octyl acetate[1]	09.254	WHO (2000) (JECFA)

[20]Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council. OJ L 1 80, 19.7.2000, p. 8.

TABLE 4 (Continued)

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA/JECFA opinion,* year
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a, 2020b
		α-Terpineol	02.014	2012a
		4-Terpinenol	02.072	
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	Menthol[2]	02.015	2016b, 2020a
		cis-p-Menthan-3-one (*d,l*-isomenthone)[3,4]	07.078	2016b, 2023c
		trans-p-Menthan-3-one[4,5] (*trans*-menthone)	07.176	
		Menthyl acetate	09.016	2016b
		Carvyl acetate	09.215	
		Dihydrocarveol[1]	02.061	WHO (2000) (JECFA)
		p-Menth-1-en-3-one[1]	07.175	2014a, CEF
		Carvone[1,6]	07.012	2014, SC
		3-Methyl-2(pent-2-*(cis)* enyl)cyclopent-2-en-1-one[1]	07.094	2016a, CEF
		p-Mentha-1,4(8)-dien-3-one[1]	07.127	2014b, CEF
13	Furanones and tetrahydrofurfuryl derivatives	2,5-Diethyltetrahydrofuran[1]	13.095	2016b, CEF
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012b, 2021
18	Allylhydroxybenzenes	Eugenol	04.003	2011
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	1-Isopropyl-4-methylbenzene (*p*-Cymene)	01.002	2015b
		1-Isopropenyl-4-methylbenzene	01.010	
		d-Limonene	01.045	
		Terpinolene	01.005	2015b, 2023c
		α-Terpinene	01.019	
		γ-Terpinene	01.020	
		Pin-2(10)-ene (β-pinene)	01.003	2016c
		Pin-2(3)-ene (α-pinene)	01.004	
		β-Caryophyllene	01.007	
		Myrcene	01.008	
		Camphene	01.009	
		3,7-Dimethyl-1,3,6-octatriene (β-ocimene)[1,7]	01.018	
		δ-Cadinene[1,8]	01.021	2011, CEF
		β-Cubebene[1,8]	01.030	
		Germacra-1(10),4(14),5-triene δ-Germacrene[1,8]	01.042	
		3,7,10-Humulatriene[1,8]	01.043	
		4(10)-Thujene (sabinene)[1]	01.059	2015a, CEF
		cis-3,7-Dimethyl-1,3,6-octatriene (*cis*-β-Ocimene)[1]	01.064	
		β-Bourbonene[1]	01.024	2015b, CEF
32	Epoxides	β-Caryophyllene epoxide[1]	16.043	2014c, CEF

*FEEDAP opinion unless otherwise indicated.

[1]Evaluated for use in food. According to Regulation (EC) 1565/2000, flavourings evaluated by JECFA before 2000 are not required to be re-evaluated by EFSA.

[2]Menthol [02.105]: The stereochemistry is not specified but the analytical data provided refer to (–)-menthol (= *l*-menthol) (EFSA FEEDAP Panel, 2016b). The same FLAVIS number [02.015] can be adequately used to identify the racemate and its isomeric forms (EFSA FEEDAP Panel, 2020a).

[3]*d,l*-Isomenthone [07.078]: two diastereoisomers (+)-isomenthone and (–)-isomenthone in *cis*-configuration. *p*-Menthan-3-one (menthone): The stereochemistry of menthone [07.059] is not specified. It possesses two chiral centres.

[4]EFSA evaluated a mixture of (+)-menthone and (–)-menthone (in *trans*-configuration [07.176]) in co-occurrence with their two diastereoisomers (+)-isomenthone and (–)-isomenthone (in *cis*-configuration [07.078]), containing approximately 25% of each (EFSA CEF Panel, 2012).

[5]*trans*-Menthone [07.176]: menthone exists only as the *trans*-isomer. Referred to in the opinion as menthone (JECFA name).

[6]Carvone [07.012]: stereochemistry not given; however, *(l)*-carvone occurs in flowering tops of *Mentha spicata* L. (EFSA Scientific Committee, 2014; Tisserand & Young, 2014). EFSA evaluated *l*-carvone [07.147] as a feed additive (EFSA FEEDAP Panel, 2016b, 2023c).

[7]β-Ocimene [01.018]: a mixture of *(E)*- and *(Z)*-isomers was evaluated (EFSA FEEDAP Panel, 2016c), containing 50%–70% *(E)*-isomer and 15–17% *(Z)*-isomer (EFSA CEF Panel, 2015b).

[8]Evaluated applying the 'Procedure' described in the Guidance on the data required for the risk assessment of flavourings to be used in or on food (EFSA CEF Panel, 2010). No longer authorised for use as flavours in food.

Four compounds listed in Table 4, δ-cadinene [01.021], β-cubebene [01.030], δ-germacrene [01.042] and 3,7,10-humulatriene [01.043] have been evaluated in Flavouring Group Evaluations 25 Revision 2 by applying the procedure described in the Guidance on the data required for the risk assessment of flavourings to be used in or on foods (EFSA CEF Panel, 2010). For these compounds, for which there is no concern for genotoxicity, EFSA requested additional sub-chronic toxicity data (EFSA CEF Panel, 2011). In the absence of these data, the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015a). As a result, these compounds are no longer authorised for use as flavours in food. For these compounds, in the absence of toxicity data, the FEEDAP Panel applies the threshold of toxicological concern (TTC) approach or read-across from structurally related substances, as recommended in the Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019).

The remaining 40 components of spearmint oil listed in Table 4, accounting on average for 89.7% of the GC area, are considered safe for use as flavourings. They are currently authorised for use in food[21] without limitations and for use in feed[22] at individual use levels higher than those resulting from the intended use in feed of the essential oil under assessment, except for *l*-carvone [07.147].[23]

The major component *l*-carvone [07.147] and *d,l*-isomenthone [07.078] were included in tolerance studies made with the mixture of flavourings referred to as 'Herbal' (EFSA FEEDAP Panel, 2023c). Linalool [02.013] and octan-3-one [07.062] were similarly tested in mixtures of flavourings named 'TuttiFrutti' and 'MilkyVanilla', respectively (EFSA FEEDAP Panel, 2020b, 2023b). Based on these studies, the FEEDAP Panel concluded that *l*-carvone [07.147] and octan-3-one [07.062] are safe at 10 mg/kg complete feed for all animal species, *d,l*-isomenthone [07.078] at 5 mg/kg, and linalool [02.013] at 30 mg/kg. By applying read-across, the FEEDAP Panel also concluded that menthone [07.176] is safe for all animal species at 5 mg/kg complete feed (EFSA FEEDAP Panel, 2023c), and that octan-3-ol [02.098] and 3-octyl acetate [09.254] are safe at 10 mg/kg complete feed (EFSA FEEDAP Panel, 2023b).

Twenty-nine volatile compounds have not been previously assessed for use as flavourings. The FEEDAP Panel notes that 25 of them[24] accounting for about 8% of the GC area are aliphatic monoterpenes or sesquiterpenes structurally related to flavourings already assessed in CG 6, CG 8, and CG 31 and a similar metabolic and toxicological profile is expected. Because of their lipophilic nature, they are expected to be rapidly absorbed from the gastro-intestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted, and not to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2012a, 2015b, 2016a, 2016b, 2016c).

The genotoxicity of *d*-limonene epoxide[25] (stereochemistry not specified), investigated in an Ames test and in an SOS Chromotest, gave negative results (Basler et al., 1989 as referenced in EFSA CEF Panel, 2014c). When V79 Chinese hamster cells were incubated with *d*-limonene epoxide, no increase in sister chromatid exchange was observed (von der Hude et al., 1991, as referenced in EFSA CEF Panel, 2014c).

The genotoxic potential of the remaining three compounds, *trans*-1-methyl-4-(1-methylvinyl)cyclohex-2-en-1-ol, *cis-p*-2,8-menthadien-1-ol and carvone-5,6-oxide, was predicted using the Organisation for Economic Co-operation and Development (OECD) QSAR Toolbox.[26] For *trans*-1-methyl-4-(1-methylvinyl)cyclohex-2-en-1-ol and *cis-p*-2,8-menthadien-1-ol, structural alerts were due to the presence of the vinyl/allyl alcohol group, and for carvone-5,6-oxide to the presence of the epoxide, ketone, aziridines and thiiranes groups. For all substances, predictions of mutagenicity by Ames test (with and without S9) were made by 'read-across' analyses of data available for similar substances to the target compounds (i.e. analogues obtained by categorisation). Read-across-based predictions were found consistently negative for all categories of analogues. On this basis, the alerts raised were discounted by the FEEDAP Panel.

3.4.1 | Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals with the essential oil under assessment were not submitted. In the absence of these data, the approach to the safety assessment of a mixture whose individual components are known is based on the safety assessment of each individual component (component-based approach). This approach requires that the mixture is sufficiently characterised and that the individual components can be grouped into assessment groups, based on structural and metabolic similarity. The combined toxicity can be predicted

[21]Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC. OJ L 267, 2.10.2012, p. 1.

[22]European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-eu-reg-comm_register_feed_additives_1831-03.pdf.

[23]*l*-Carvone [07.147] is authorised for use in all animal species with a maximum content of 10 mg/kg complete feed. Commission Implementing Regulation (EU) 2024/1989 of 24 July 2024. OJ L, 2024/1989, 24.7.2024.

[24]*trans*-Sabinene hydrate, viridiflorol, δ-terpineol, *cis*-sabinene hydrate (CG 6); *cis*-carveol, *trans*-carveol, *cis*-dihydrocarvone, *trans*-dihydrocarvone, *trans*-dihydrocarvylacetate, isomenthol, neoisomenthol, neoisomenthyl acetate, neodihydrocarveol, isopeiperitenol (CG 8); *trans*-3,7-dimethyl-1,3,6-octatriene (*trans*-β-ocimene), *trans*-β-farnesene, pseudolimonene, *p*-1-menthene, β-elemene, α-thujene,α-copaene, β-copaene, γ-muurolene, 4(15),10(14)-cadinadiene, bicyclosesquiphellandrene.

[25]Minor component (listed in footnote 16) occurring in three batches of the oil under assessment (0.05%–0.09%).

[26]Technical dossier/Supplementary information December 2024/Annex_VII_SIn_reply spearmint_oil_QSAR.

using the dose addition assumption within an assessment group, taking into account the relative toxic potency of each component (EFSA Scientific Committee, 2019).

As the additive under assessment is a fully defined mixture (the identified components represent on average 99.2% of the GC area, see Section 3.3.1), the FEEDAP Panel applied a component-based approach to assess the safety for target species of the essential oil.

The oil under assessment contains by specification up to 87% of *l*-carvone [07.147] and up to 0.7% of *d,l*-isomenthone [07.078], which are assessed separately from the other components of the oil, based on the result of tolerance trials with the mixture of flavourings 'Herbal' (EFSA FEEDAP Panel, 2023c). Similarly, linalool [02.013] and octan-3-one [07.062], which were included in tolerance studies with mixtures of flavourings 'TuttiFrutti', and 'MilkyVanilla' (EFSA FEEDAP Panel, 2020b, 2023b) are assessed separately. The structurally related compounds octan-3-ol [02.098] and 3-octyl acetate [09.254] are assessed together with octan-3-one [07.062]. The remaining identified components are assessed using the component-based approach.

3.4.1.1 | *Components tested in tolerance trials with mixtures of flavourings*

l-Carvone and carvyl derivatives

The FEEDAP Panel performed a group assessment of *l*-carvone and carvyl derivatives present in spearmint oil: *cis*-carveol, *trans*-carveol, *cis*-dihydrocarvone, *trans*-dihydrocarvone, dihydrocarveol (mixture of isomers not specified), neodihydrocarveol (mixture of isomers not specified), *(1R,5R)*-carvyl acetate, *trans*-dihydrocarvyl acetate, *p*-menth-1-en-3-one [07.175] and isopiperitenol.

l-Carvone [07.147] was assessed in tolerance studies with a mixture of flavourings referred to as 'Herbal' in chickens for fattening, piglets, cattle for fattening and salmons. The tolerance studies showed that *l*-carvone was safe for the target species at 10 mg/kg complete feed (EFSA FEEDAP Panel, 2023c). The conclusions of the tolerance study with *l*-carvone were applied to all carvyl derivatives by applying read-across.

In a worst-case scenario, in which *l*-carvone is present at the highest specifications of 87% and the other carvyl derivatives are assumed to be all present at the highest analysed concentration in spearmint oil, their sum would be up to 100%. Considering the proposed maximum use levels (25–100 mg/kg complete feed), the highest concentration in feed of the sum of carvyl derivatives would range from 25 to 100 mg/kg complete feed, which is above the safe level of 10 mg/kg complete feed for *l*-carvone. On this basis, the FEEDAP Panel concludes that the use of spearmint oil is safe at a maximum use level of 10 mg/kg complete feed for all animal species, with regard to the presence of *l*-carvone and carvyl derivatives.

d,l-Isomenthone, linalool, octan-3-one, octan-3-ol and 3-octyl acetate

The highest concentration in feed of the sum of *d,l*-isomenthone [07.078] and menthone [07.176] resulting from the use of the additive at the maximum proposed use levels would be 0.56–2.24 mg/kg complete feed.[27] This concentration is below the safe level of 5 mg/kg complete feed experimentally established for *d,l*-isomenthone in tolerance trials with the mixture of flavourings 'Herbal' and extrapolated to menthone by applying read-across (EFSA FEEDAP Panel, 2023c).

The highest concentration in feed of linalool [02.013] resulting from the use of the additive at the maximum proposed use levels would be 0.035–0.14 mg/kg complete feed.[28] This is below the value of 30 mg/kg complete feed established by the tolerance trials with the mixture of flavourings 'TuttiFrutti' as safe for all animal species (EFSA FEEDAP Panel, 2020b).

The highest concentration in feed of the sum of octan-3-one [07.062], octan-3-ol [02.098] and 3-octyl acetate [09.254] resulting from the use of the additive at the maximum proposed use levels would be 0.22–1.09 mg/kg complete feed.[29] These concentrations are below the value of 10 mg/kg complete feed experimentally established for octan-3-one in tolerance trials with the mixture of flavourings 'MilkyVanilla' and extrapolated to octan-3-ol by applying read-across (EFSA FEEDAP Panel, 2023b).

3.4.1.2 | *Components other than those tested in tolerance trials*

Based on considerations related to structural and metabolic similarities, the remaining components were allocated to 10 assessment groups, corresponding to the chemical groups (CGs) 1, 4, 5, 6, 8, 13, 16, 18, 31 and 32, as defined in Annex I of Regulation (EC) No 1565/2000. For CG 31 (aliphatic and aromatic hydrocarbons), sub-assessment groups as defined in Flavouring Group Evaluation 25 (FGE.25) and FGE.78 were established (EFSA CEF Panel, 2015a, 2015b). The allocation of the components to the (sub)assessment groups is shown in Table 5 and in the corresponding footnote.

[27]Calculated considering the maximum proposed use level of 25–100 mg/kg complete feed and the highest concentration of *d,l*-isomenthone (0.70%) and menthone (1.54%) in the six batches.

[28]Calculated considering the maximum proposed use level of 25–100 mg/kg complete feed and the highest concentration of linalool (0.14%) in the six batches.

[29]Calculated considering the maximum proposed use level of 25–100 mg/kg complete feed and the highest analysed concentrations of octan-3-one (0.08%), octan-3-ol (0.60%) and 3-octyl acetate (0.41%) in the six batches.

For hazard characterisation, each component of an assessment group was first assigned to the structural class according to Cramer classification using Toxtree (version 3.1.0, May 2018[30]). For some components in the assessment group, toxicological data were available to identify no observed adverse effect levels (NOAELs). Structural and metabolic similarity among the components in the assessment group was assessed to explore the application of read-across, allowing extrapolation from a known NOAEL of a component of an assessment group to the other components of the group with no available NOAEL or, if sufficient evidence were available for members of a (sub-)assessment group, to derive a (sub-)assessment group NOAEL.

Toxicological data of subchronic studies, from which NOAEL values could be identified, were available for the following components: 127 mg/kg bw per day for hex-3*(cis)*-en-1-ol [02.056] in CG 4 (EFSA FEEDAP Panel, 2016a), 38 mg/kg bw per day for isopulegol [02.067] in CG 5 (EFSA FEEDAP Panel, 2020), 250 mg/kg bw per day for terpineol [02.230][31] in CG 6 (EFSA FEEDAP Panel, 2012a), 375 mg/kg bw per day for menthol [02.015] in CG 8 (EFSA FEEDAP Panel, 2016b), 100 mg/kg bw per day for 1,8-cineole [03.001] in CG 16 (EFSA FEEDAP Panel, 2021), 300 mg/kg bw per day for eugenol [04.004] in CG 18 (EFSA FEEDAP Panel, 2011), 44 mg/kg bw per day for myrcene [01.008], 154 mg/kg bw per day for *p*-cymene [01.002], 250 mg/kg bw per day for *d*-limonene [01.046] and 222 mg/kg bw per day for β-caryophyllene [01.007] in CG 31 (EFSA FEEDAP Panel, 2015b, 2016c) and 109 mg/kg bw per day for β-caryophyllene epoxide [16.043] in CG 32 (EFSA CEF Panel, 2014b). For α-terpinene [01.019], the FEEDAP Panel identified a NOAEL of 60 mg/kg bw per day based on maternal toxicity (reduced body weight gain) in a teratogenicity study in rats. The NOAEL of 60 mg/kg bw per day was divided by a factor of 2 to take account of the nature of the study (see Araujo et al., 1996; ECHA, 2018).

For CG 1, a group NOAEL of 120 mg/kg per day was identified from the toxicological data available for several compounds (EFSA FEEDAP Panel, 2013), which is applied to octan-1-ol [02.006], decan-1-ol [02.024], octyl acetate [09.007] and decanal [05.010] in the current assessment.

In CG 6, a NOAEL of 250 mg/kg bw per day was identified for terpineol [02.230] and divided by a factor of 2 to take account of the nature of the study (EFSA FEEDAP Panel, 2012a). The resulting value of 125 mg/kg bw per day was used as the reference point for terpinyl derivatives, 4-terpinenol [02.072], α-terpineol [02.014] and δ-terpineol.

In CG 8, the NOAEL of 375 mg/kg bw per day for menthol [02.015] has already been applied to menthyl acetate [09.016] (EFSA FEEDAP Panel, 2016b). In the current assessment, the NOAEL is also extrapolated to isomenthol, neoisomenthol and neoisomenthyl acetate.

Considering the structural and metabolic similarities, the NOAELs for the representative compounds in CG 31, myrcene [01.008], *d*-limonene [01.045] and β-caryophyllene [01.007] were applied, respectively, using read-across to the compounds within sub-assessment groups II (*cis*-β-ocimene [01.064], *trans*-β-ocimene, *trans*-β-farnesene), III (terpinolene [01.005], γ-terpinene [01.020] and *p*-1-menthene) and V (β-bourbonene [01.024], α-pinene [01.004], β-pinene [01.003], sabinene [01.059], β-cubebene [01.030], δ-cadinene [01.021], γ-muurolene, β-copaene, α-copaene, α-thujene, camphene [01.009], bicyclosesquiphellandrene),[32] respectively (EFSA CEF Panel, 2015a, 2015b).

The NOAEL of 222 mg/kg bw per day for β-caryophyllene [01.007] was also applied to *trans*-sabinene hydrate, *cis*-sabinene hydrate and viridiflorol in CG 6, and 3,7,10-humulatriene [01.043] in CG 31, VI.[33] For viridiflorol, the NOAEL of β-caryophyllene [01.007] was divided by a factor of 2 to take account of the uncertainty in read-across due to the presence of an additional cyclopropane ring in the molecule. Similarly for 3,7,10-humulatriene, the NOAEL of β-caryophyllene was divided by a factor of 2 to take account of the uncertainty in read-across due to differences in the structure (extrapolation from a tricyclic to a macrocyclic non-aromatic compound) (EFSA FEEDAP Panel, 2023).

For the remaining compounds,[34] toxicity studies performed with the compounds under assessment were not available and read-across was not possible. Therefore, the TTC approach was applied (EFSA FEEDAP Panel, 2017b; EFSA Scientific Committee, 2019).

As the result of the hazard characterisation, a reference point was identified for each component in the assessment group based on the toxicity data available (NOAEL from in vivo toxicity study or read-across) or from the 5th percentile of the distribution of NOAELs of the corresponding Cramer Class (i.e. 3, 0.91 and 0.15 mg/kg bw per day, respectively, for Cramer Class I, II and III compounds, Munro et al., 1996). Reference points selected for each compound are shown in Table 5.

For each component in the assessment group, exposure in target animals (expressed as mg/kg bw per day) was estimated considering the maximum use level of the additive of 10 mg/kg complete feed (considered safe based on the presence of *l*-carvone and carvyl derivatives), the percentage of the component in the oil and the default values for body weight and feed intake according to the guidance on the safety of feed additives for target species (EFSA FEEDAP Panel, 2017b). For the compounds covered by specifications (*d*-limonene and β-bourbonene, see Table 1), the indicated maximum specified concentration is used for the calculation of exposure. For the other components, the highest analysed concentration is used.

[30]Toxtree includes both the original Cramer rule base with the 33 structural rules (Cramer et al., 1978) and an extended rule base with five additional rules which were introduced to overcome misclassification (in Class I or Class II) of several substances with low NOAELs. https://toxtree.sourceforge.net/.

[31]Terpineol is a mixture of four structural isomers: α-terpineol [02.014], β-terpineol, γ-terpineol and 4-terpinenol [02.072]. α-Terpineol [02.014], is defined as a mixture of *(R)*-(+)-α-terpineol and *(S)*-(−)-α-terpineol.

[32]Some of these compounds are not listed in Table 5 because their individual margin of exposure (MOE) was > 50,000.

[33]Grouping the components *trans*-sabinene hydrate, *cis*-sabinene hydrate, viridiflorol (CG 6), and 3,7,10-humulatriene [01.043] (CG 31, VI) with β-caryophyllene [01.007] and the other components assessed based on the same NOAEL of 222 mg/kg bw pe day in CG 31 ,V had no impact on the outcome of the assessment (MOET 1000).

[34]CC I (3 mg/kg bw per day): *cis-p*-2,8-menthadien-1-ol, *trans*-1-methyl-4-(1-methylvinyl)cyclohex-2-en-1-ol (CG 6); β-elemene, pseudolimonene, 1-isopropenyl-4-methylbenzene, 4(15),10(14)-cadinadiene, germacra-1(10),4(14),5-triene [01.042] (CG 31); CC II (0.91 mg/kg bw per day): 3-methyl-2(pent-2-enyl)cyclopent-2-en-1-one, *p*-mentha-1,4(8)-dien-3-one (CG 8); 2,5-diethyltetrahydrofuran [13.095] (CG 13); CC III (0.15 mg/kg bw per day): carvone-5,6-oxide.

For risk characterisation, the margin of exposure (MOE) was calculated for each component as the ratio between the reference point and the exposure. For an assessment group, (i) when a group reference point is available, a group MOE was calculated for the combined intake; (ii) when different reference points are available for the components, the combined (total) margin of exposure (MOET) was calculated as the reciprocal of the sum of the reciprocals of the MOE for the individual substances (EFSA Scientific Committee, 2019). A MOE(T) > 100 allowed for interspecies and intra-individual variability. The compounds resulting individually in an MOE > 50,000 were not further considered in the assessment group as their contribution to the MOE(T) is negligible. They are listed in the footnote.[35]

The approach to the safety assessment of spearmint oil is shown in Table 5 for chickens for fattening, which is the species with the highest ratio of feed intake/body weight and represents the worst-case scenario among the target species. The calculations were done at the maximum use level of 10 mg/kg complete feed, considered safe based on the presence of *l*-carvone and carvyl derivatives.

TABLE 5 Compositional data, intake values (calculated for chickens for fattening at 10.0 mg/kg complete feed), reference points, margin of exposure (MOE) for the individual components of spearmint oil classified according to assessment groups, and combined margin of exposure (MOET) for each assessment group.

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS-No**	**Highest concentration in the oil**	**Highest concentration in feed**	**Daily intake[1]**	**Cramer class[2]**	**NOAEL[3]**	**MOE[4]**	**MOET[5]**
Constituent	**–**	**%**	**mg/kg**	**mg/kg bw per day**	**–**	**mg/kg bw per day**	**–**	**–**
CG 5								
Isopulegol	02.067	0.12	0.012	0.0011	(I)	**38**	35,274	
CG 6								
4-Terpinenol	02.072	0.95	0.095	0.0085	(I)	125[6]	14,657	
α-Terpineol	02.014	0.56	0.056	0.0050	(I)	125[6]	25,088	
cis-p-2,8-Menthadien-1-ol	–	0.13	0.013	0.0012	I	*3*	2532	
trans-1-Methyl-4-(1-methylvinyl) cyclohex-2-en-1-ol	–	0.10	0.010	0.0009	I	*3*	3481	
MOET CG 6								**1265**
CG 8								
Menthol	02.015	2.86	0.286	0.0257	(I)	**375**	14,606	
3-Methyl-2(pent-2-enyl) cyclopent-2-en-1-one	07.094	0.26	0.026	0.0023	II	*0.91*	390	
p-Mentha-1,4(8)-dien-3-one	07.127	0.03	0.003	0.0003	II	*0.91*	3379	
MOET CG 8								**341**
CG 13								
2,5-Diethyltetrahydrofuran	13.095	0.15	0.015	0.0014	II	*0.91*	671	
CG 16								
1,8-Cineole	03.001	1.74	0.174	0.0156	(II)	**100**	6409	
CG 31, II (Acyclic alkanes)								
Myrcene	01.008	3.00	0.300	0.0269	(I)	**44**	1635	
trans-β-Farnesene	–	0.80	0.080	0.0072	(I)	44	6142	
cis-β-Ocimene	01.064	0.14	0.014	0.0013	(I)	44	34,516	
Group MOE CG 31, II							**1245**	
CG 31, III (Cyclohexene hydrocarbons)								
d-Limonene	01.046	25.0	2.500	0.2244	(I)	**250**	1114	
β-Elemene	–	0.24	0.024	0.0022	I	*3*	1375	

(Continues)

[35]Compounds included in the assessment groups but not reported in the table: decan-1-ol [02.024], octan-1-ol [02.006], octyl acetate [09.007], octanal [05.009] (CG 1); hex-3(*cis*)-en-1-ol [02.056] (CG 4); *trans*-sabinene hydrate, viridiflorol, δ-terpineol, *cis*-sabinene hydrate (CG 6); menthyl acetate, isomenthol, neoisomenthol, neoisomenthyl acetate [02.061] (CG 8); eugenol (CG 18); *trans*-β-ocimene (CG 31, II); γ-terpinene [01.020], terpinolene [01.005], *p*-1-menthene (CG 31, III); β-cubebene [01.030], δ-cadinene [01.021], γ-muurolene, β-copaene,α-copaene, α-thujene, camphene [01.009], bicyclosesquiphellandrene (CG 31, V); 3,7,10-humulatriene [01.043] (CG 31, VI); *trans*-limonene epoxide (CG 32).

TABLE 5 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS-No**	**Highest concentration in the oil**	**Highest concentration in feed**	**Daily intake[1]**	**Cramer class[2]**	**NOAEL[3]**	**MOE[4]**	**MOET[5]**
Constituent	**–**	**%**	**mg/kg**	**mg/kg bw per day**	**–**	**mg/kg bw per day**	**–**	**–**
α-Terpinene	01.019	0.24	0.024	0.0022	(I)	**30**[7]	13,924	
Pseudolimonene	–	0.19	0.019	0.0017	II	*3*	1806	
MOET CG 31,III								**444**
CG 31, IVe (Benzene hydrocarbons, alkyl)								
p-Cymene	01.002	0.68	0.068	0.0061	(I)	154	25,080	
1-Isopropenyl-4-methylbenzene	01.010	0.07	0.007	0.0006	I	*3*	4914	
MOET CG 31, IVe								**4109**
CG 31, V (Bi-, tricyclic, non aromatic hydrocarbons)								
β-Bourbonene	01.024	2.00	0.200	0.0180	(I)	222	12,365	
β-Caryophyllene	01.007	1.49	0.149	0.0133	(I)	**222**	16,653	
α-Pinene	01.004	1.45	0.145	0.0130	(I)	222	17,066	
β-Pinene	01.003	1.44	0.144	0.0129	(I)	222	17,209	
Sabinene	01.059	0.92	0.092	0.0083	(I)	222	26,909	
4(15),10(14)-Cadinadiene	–	0.22	0.022	0.0020	I	*3*	1533	
MOET CG 31, V								**1056**
CG 31, VI (Macrocyclic non aromatic hydrocarbons)								
Germacra-1(10),4(14),5-triene	01.042	1.05	0.105	0.0094	I	*3*	318	
CG 32								
β-Caryophyllene epoxide	16.043	0.34	0.034	0.0030	(III)	**109**	36,244	
Carvone-5,6-oxide	–	0.13	0.013	0.0012	III	*0.15*	125	
MOET CG 32								**124**

Abbreviations: MOE, margin of exposure; MOET, combined (total) MOE; NOAEL, no observed adverse effect level.

[1]Rounded intake values are shown in the Table.

[2]When a NOAEL value is available or read-across is applied, the allocation to the Cramer class is put into parentheses.

[3]Values **in bold** refer to those components for which the NOAEL value was available, values *in italics* are the 5th percentile of the distribution of NOAELs of the corresponding Cramer Class, other values (plain text) are NOAELs extrapolated by using read-across.

[4]The MOE for each component is calculated as the ratio of the reference point (no observed adverse effect level, NOAEL) to the intake (non-rounded values are use in the calculations). When a group reference point is available, a group MOE is calculated for the combined intake. Group MOE values are reported **in bold**.

[5]The combined margin of exposure (MOET) is calculated for each assessment group as the reciprocal of the sum of the reciprocals of the MOE for the individual substances. MOET values are reported **in bold**.

[6]A factor of 2 was applied to the NOAEL of 250 mg/kg bw per day for terpineol because of the nature of the study.

[7]A factor of 2 was applied to the NOAEL of 60 mg/kg bw per day for α-terpinene because of the nature of the study.

As shown in Table 5, for all assessment groups, the MOE(T) calculated for chickens for fattening at the use level of the additive of 10 mg/kg complete feed (see Section 3.4.1.1) was > 100. The lowest MOET of 124 was calculated for CG 32. The MOET for CG 32 compounds calculated for the other target species at 10 mg/kg complete feed are summarised in Table 6.

TABLE 6 Combined margin of exposure (MOET) for the assessment group CG 32 calculated for the different target animal species/categories at the reduced use level of 10 mg/kg complete feed (calculated considering the content of *l*-carvone and carvyl derivatives).

Animal species/ categories	Daily feed intake (g DM/kg bw)	Use level (mg/kg complete feed)[1]	Lowest MOET CG 32
Chickens for fattening	79	10	124
Laying hens	53	10	185
Turkeys for fattening	59	10	166
Pigs for fattening	44	10	223
Piglets	37	10	265

TABLE 6 (Continued)

Animal species/ categories	Daily feed intake (g DM/kg bw)	Use level (mg/kg complete feed)[1]	Lowest MOET CG 32
Sows	30	10	327
Veal calves (milk replacer)	19	10	557
Cattle for fattening	20	10	490
Dairy cows	31	10	316
Sheep/goats	20	10	490
Horses	20	10	490
Rabbits	50	10	196
Salmonids	18	10	544
Dogs	17	10	576
Cats	20	10	490
Ornamental fish	5	10	1959

[1]Complete feed containing 88% DM, milk replacer 94.5% DM.

At the use level of 10 mg/kg complete feed, the MOET exceeds the value of 100 for all animal species. Because glucuronidation is an important metabolic pathway to facilitate the excretion of the components of the essential oil and considering that cats have an unusually low capacity for glucuronidation, particularly for aromatic compounds (Court & Greenblatt, 1997; Lautz et al., 2021), the use of spearmint oil as an additive in cat feed needs a wider margin of exposure. A MOET of 490 (rounded to 500) is considered adequate. For all the animal species and categories listed in Table 6, spearmint oil is considered safe when used as feed additive at 10 mg/kg complete feed.

3.4.1.3 | *Overall evaluation*

When considering the assessment of the individual components or groups of components of spearmint oil, the maximum safe concentration of the additive in feed for all animal species was 10 mg/kg complete feed based on the presence of *l*-carvone and carvyl derivatives (see Section 3.4.1.1). This level is extrapolated to all animal species.

No specific use levels have been proposed by the applicant for the use of spearmint oil in water for drinking. The FEEDAP Panel considers that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

3.4.1.4 | *Conclusions on the safety for the target species*

The FEEDAP Panel concludes that spearmint oil is safe for all animal species at 10 mg/kg complete feed.

The FEEDAP Panel considers that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

3.4.2 | Safety for the consumer

Spearmint oil is added to a wide range of food categories for flavouring purposes. Fenaroli's handbook reports use levels for the spearmint oil ranging from 39 to 66,700 mg/kg in food and beverages.

Most of the individual constituents of the essential oil under assessment are currently authorised as food flavourings without limitations and have already been assessed for consumer safety when used as feed additives in animal production (see Table 4, Section 3.4).

No data on residues in products of animal origin were made available for any of the constituents of the essential oil. However, the Panel recognises that the constituents of spearmint oil are expected to be extensively metabolised and excreted in the target species. For the major component *l*-carvone, the available data in laboratory animals and humans indicate that it is absorbed, metabolised by oxidation and excreted and is not expected to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2016b). Consequently, relevant residues in food products are unlikely.

Considering the above and the reported human exposure due to the direct use of spearmint oil in food (Burdock, 2009), the FEEDAP Panel considers that the consumption of products from animals given spearmint oil at the maximum use levels proposed by the applicant would be unlikely to significantly increase human background exposure.

The use of spearmint oil in animal nutrition under the proposed conditions of use is considered safe for the consumer.

3.4.3 | Safety for the user

No specific data were provided by the applicant regarding the safety of the additive for users.

The applicant provided a safety data sheet,[36] which identified hazards for dermal and eye irritation and dermal and respiratory sensitisation.

The FEEDAP Panel considers spearmint oil to be as irritant to skin and eyes and to be both a dermal and respiratory sensitiser. Exposure of users by any route is considered a risk.

3.4.4 | Safety for the environment

Mentha spicata L. occurs in the wild and is native to and widely distributed over Europe. It is also cultivated in many European countries. The use of spearmint oil in animal feed under the proposed conditions of use is not expected to pose a risk to the environment.

3.5 | Efficacy

Spearmint oil from *Mentha spicata* L. is listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by FEMA with the reference number 3032.

Since spearmint oil is recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

4 | CONCLUSIONS

Spearmint oil from *Mentha spicata* L. may be produced from plants of different origins and by various processes resulting in preparations with different compositions and toxicological profiles. Thus, the following conclusions apply to essential oils obtained by steam distillation from the aerial parts of *Mentha spicata* L., including oils produced by fractional distillation and subsequent blending of fractions to meet the intended specifications.

The FEEDAP Panel concludes that spearmint oil from the aerial parts of *Mentha spicata* L. is safe for all animal species at a maximum use level of 10 mg/kg complete feed. The FEEDAP Panel considers that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

The use of the additive at the proposed conditions of use is safe for the consumers and the environment.

Regarding user safety, the essential oil under assessment should be considered as irritant to skin and eyes and as a dermal and respiratory sensitiser. Exposure of users by any route is considered a risk.

Since spearmint oil is recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

5 | DOCUMENTATION PROVIDED TO EFSA/CHRONOLOGY

Date	Event
23/11/2010	Dossier received by EFSA. Botanically defined flavourings from Botanical Group 01 – Lamiales for all animal species and categories. Submitted by Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)
03/01/2011	Reception mandate from the European Commission
06/01/2011	Application validated by EFSA – Start of the scientific assessment
01/04/2011	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: analytical methods*
08/01/2013	Reception of supplementary information from the applicant - Scientific assessment remains suspended
26/02/2013	EFSA informed the applicant (EFSA ref. 7150727) that, in view of the workload, the evaluation of applications on feed flavourings would be re-organised by giving priority to the assessment of the chemically defined feed flavourings, as agreed with the European Commission
24/06/2015	Technical hearing during risk assessment with the applicant according to the 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products': data requirement for the risk assessment of botanicals

[36]Technical dossier/Supplementary information December 2024/Annex_VIII_SIn_reply_spearmint_oil_MSDS. Acute toxicity (oral) (H302, category 4), skin irritation (H315, category 2), eye irritation (H319, category 2), skin sensitization (H317, category 1), in accordance with the criteria outlined in Annex I of 1272/2008/EC (CLP/EU-GHS).

Date	Event
27/02/2019	Partial withdrawal by applicant (EC was informed) for the following additives: Thyme leaves gratiola tincture, spike lavender oil, melissa oil, pennyroyal oil, basil oil and savoury summer oil
30/06/2021	EFSA informed the applicant that the evaluation process restarted
08/07/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety for target species, safety for the consumer, safety for the user and environment*
28/09/2023	Partial withdrawal of the application for the following additive: Spanish majoram oil
08/07/2024	Partial withdrawal of the application for the following additives: lilac chaste tree extract and savoury summer tincture
26/08/2024	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives. Partial report related to seven additives: Spanish sage oil, peppermint oil, thymus origanum oil, patchouli oil, clary sage oil, lavender oil and sage oil
27/08/2024	Reception of supplementary information from the applicant (letter of agreement)
16/12/2024	Partial withdrawal of the application for the following additives: devils claw extract (wb), balm leaves extract (sb), olive extract (sb)
17/12/2024	Reception of supplementary information from the applicant (partial dataset: spearmint oil) - Scientific assessment remains suspended
18/06/2025	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives. Partial report related to 11 additives: cornmint oil, spearmint oil, thyme oil, rosemary oil, marjoram oil, rosemary tincture, basil tincture, lavender tincture, peppermint tincture, sage tincture and wild thyme tincture
26/06/2025	The application was split and a new EFSA-Q-2025-00405 was assigned to the additive included in the present assessment. Scientific assessment re-started for the additive included in the present assessment
18/11/2025	Opinion adopted by the FEEDAP Panel on spearmint oil (EFSA-Q-2025-00405). End of the Scientific assessment for the additive included in the present assessment. The assessment of other additives in BGD 01 is still ongoing

ABBREVIATIONS

BDG	botanically defined group
BW	body weight
CAS	Chemical Abstracts Service
CDG	Chemically defined group
CEF	EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CG	chemical group
CLP	Classification, Labelling and Packaging
CoE	Council of Europe
DM	dry matter
ECHA	European Chemicals Agency
EMA	European Medicines Agency
EURL	European Union Reference Laboratory
FAF	EFSA Panel on Food Additives and Flavourings
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FFAC	Feed Flavourings authorisation Consortium of FEFANA (EU Association of Specialty Feed Ingredients and their Mixtures)
FEMA	Flavour Extract Manufacturers Association
FGE	food group evaluation
FLAVIS	The EU Flavour Information System
FL-no	FLAVIS number
GC–MS	Gas chromatography–mass spectrometry
GC-FID	Gas chromatography-flame ionisation detection
ISO	International Organisation for Standardisation
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
MOE	margin of exposure
MOET	combined (total) margin of exposure
NOAEL	no observed adverse effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PhEur	European Pharmacopoeia
QSAR	Quantitative Structure Activity Relationship
TTC	threshold of toxicological concern
WHO	World Health Organization

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REQUESTOR

European Commission

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