Adopted: 17 September 2024

DOI: 10.2903/j.efsa.2024.9017

efsa JOURNAL

SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of an essential oil derived from the flowering tops of *Lavandula angustifolia* Mill. (lavender oil) for use in all animal species (FEFANA asbl)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | **Roberto Edoardo Villa** | **Giovanna Azimonti** | **Eleftherios Bonos** | **Henrik Christensen** | **Mojca Durjava** | **Birgit Dusemund** | **Ronette Gehring** | **Boet Glandorf** | **Maryline Kouba** | **Marta López-Alonso** | **Francesca Marcon** | **Carlo Nebbia** | **Alena Pechová** | **Miguel Prieto-Maradona** | **Ilen Röhe** | **Katerina Theodoridou** | **Maria de Lourdes Bastos** | **Paul Brantom** | **Andrew Chesson** | **Josef Schlatter** | **Johannes Westendorf** | **Paola Manini**

Correspondence: feedap@efsa.europa.eu

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

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 fresh flowering tops of *Lavandula angustifolia* Mill. (lavender 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 proposed use levels in complete feed of 30 mg/kg for dogs and ornamental fish. For the other target species, the calculated safe concentrations were 9 mg/kg for chickens for fattening, 13 mg/kg for laying hens, 12 mg/kg for turkeys for fattening, 19 mg/kg for pigs for fattening, 16 mg/kg for piglets, 23 mg/kg for sows, 39 mg/kg for veal calves (milk replacer) and salmonids, 35 mg/kg for cattle for fattening, sheep/goats and horses, 22 mg/kg for dairy cows, 14 mg/kg for rabbits and 7 mg/kg for cats. These conclusions were extrapolated to other physiologically related species. For any other species, the additive is safe at 7 mg/kg complete feed. The use of lavender oil in water for drinking was considered safe provided that the total daily intake does not exceed the daily amount considered safe when consumed via feed. The use of lavender oil 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. Since the oil of the flowering tops of *L. angustifolia* 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

flavouring compounds, *Lavandula angustifolia* Mill., lavender oil, linalool, linalyl acetate, sensory additives

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CONTENTS

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 addition, 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 seven years after the entry into force of this Regulation.

The European Commission received a request from 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 chastetree extract, lilac chastetree 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 nine 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 32 additives under application: lavender oil from *L. angustifolia*,[5] *L. angustifolia* × *latifolia* for use in all animal species.

The remaining 31 additives belonging to 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 deleted (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 lavender oil form the fresh flowering tops of *L. angustifolia*, when used under the proposed conditions of use (see Section 3.3.3).

1.2 | Additional information

Lavender oil from *L. angustifolia* Mill., *L. angustifolia* × *latifolia* 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[6] in support of the authorisation request for the use of lavender oil from *L. angustifolia* as a feed additive. EFSA received directly from the applicant the technical dossier in support of this application. The dossier was received on 22 May 2024 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2024-00306.[7]

[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 13/03/2013, 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).
[4]Register of feed additives, Annex II, withdrawn by OJ L162, 10.5.2021, p. 5.
[5]Accepted name: *Lavandula angustifolia* Mill.
[6]Dossier reference: FAD-2010-0137.
[7]The original application EFSA-Q-2010-0137 was split on 22/05/2024 and a new EFSA-Q-2024-00306 was generated.

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.

Many of the components of the essential oil under assessment have been already 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 additives belonging to BDG 01, including the current one under assessment.[8]

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. The evaluation report is related to the methods of analysis for each feed additive included in BDG 01 – Lamiales. During the assessment, upon request of EFSA, the EURL issued a partial report,[9] which included the additive under assessment. In particular, for the characterisation of lavender oil the EURL recommended a method based on gas chromatography with flame ionisation detection (GC–FID) for the quantification of the phytochemical markers *linalyl acetate* and *linalool* in *lavender oil*.[10]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lavender oil from *L. angustifolia* is in line with the principles laid down in Regulation (EC) No 429/2008[11] 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 that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2012), 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, 2019a), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023a), 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, lavender oil, is an essential oil obtained from the fresh flowering tops[12] of *L. angustifolia* Mill. and is intended for use as a sensory additive (functional group: flavouring compounds) in feed and in water for drinking for all animal species. No data were submitted for any essential oil from *L. angustifolia* × *latifolia*.

3.1 | Origin and extraction

L. angustifolia Mill. is a perennial flowering shrub belonging to the family Lamiaceae. The term *Lavandula officinalis* Chaix is a widely encountered synonym of *L. angustifolia* subsp. *angustifolia*. Despite being commonly referred to as English lavender, *L. angustifolia* is native to France, Spain and Italy, with only later introductions into England. It is characterised by its purple flowers produced in spikes at the terminus of leafless stems. Many species of lavender are grown as commercial crops and, because of demand by the fragrance, speciality food and herbal medicinal industries, many hybrid varieties with improved yield and differing in their sensory properties have been developed. *L. angustifolia* itself produces a relatively low yield of flower heads (and consequently essential oil) compared to the modern lavandin hybrids (*L. angustifolia* crossed with the spike lavender *Lavandula latifolia* Medik.), but its essential oil is said to be of 'better quality'.

The essential oil is extracted from the fresh flowering tops of *L. angustifolia* by steam distillation. The applicant mentioned that dry material may also be used (information from supplier). However, no data were provided for essential oil obtained from dried material, which is not covered by the current assessment. The volatile constituents are condensed and then separated from the aqueous phase by decantation.

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

[9]Additives included in the partial report: Spanish sage oil, peppermint oil, thymus origanum oil, patchouli oil, clary sage oil, lavender oil and sage oil.

[10]Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

[11]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.

[12]The applicant mentioned that dry material may also be used (information from supplier). No data were provided for essential oil obtained from dried material.

3.2 | Uses other than feed flavouring

While there is no specific EU authorisation for any *L. angustifolia* preparation when used to provide flavour in food, according to Regulation (EC) No 1334/2008[13] 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'.

'Lavender flowers (Lavandulae flos)' and 'Lavender oil (Lavandulae aetheroleum)' from *Lavandula angustifolia* Mill. are described in monographs of the European Pharmacopoeia 11.4 (PhEur, 2024a, 2024b) and of the European Medicines Agency (EMA, 2012a, 2012b) for medicinal uses.

3.3 | Characterisation

3.3.1 | Characterisation of lavender oil

The essential oil is obtained from *L. angustifolia* sourced from Bulgaria or Spain and is a yellow to very pale-yellow liquid with a characteristic odour of lavender. Lavender oil is identified with the single Chemical Abstracts Service (CAS) number 8000-28-0, the European Inventory of Existing Commercial Chemical Substances (EINECS) number 283-995-2, the Flavor Extract Manufacturers Association (FEMA) number 2622 and the Council of Europe (CoE) number 257. In four batches of the additive, the refractive index (20°C) ranged between 1.4575 and 1.4606. In other three batches, compliance with the proposed specification was stated for the refractive index (1.457–1.464, 20°C) and specific gravity (830–930 kg/m^3, 20°C).[14]

For lavender oil, the specifications used by the applicant are based on those developed by the International Organization for Standardization (ISO) 3515:2002 for the oil of lavender, [*L. angustifolia* Mill.][15] and those in the European Pharmacopeia for lavender oil [*L. angustifolia* Mill.],[16] which were adapted to reflect the concentrations of selected volatile components. Four components contribute to the specifications as shown in Table 1, with linalyl acetate and linalool[17] selected as the phytochemical markers. The analysis of four batches of the additive showed compliance with these specifications when analysed by GC–FID and expressed as percentage of gas chromatographic peak area (% GC area).[18]

TABLE 1 Constituents of lavender oil, as defined by specifications and batch to batch variation based on the analysis of four 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[a]**	**Mean**	**Range**
Linalyl acetate[b]	115–95-7	09.013	25–47	37.05	29.04–45.90
Linalool[b]	78–70-6	02.013	20–45	31.16	23.17–38.36
4-Terpinenol	562–74-3	02.074	0.1–8	2.29	0.41–4.31
(Z)-β-Ocimene[c]	3338-55-4	01.064	< 10	2.72	1.16–4.29
Total				73.53	67.80–78.59[d]

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

[a]Specifications defined based on GC-FID analysis.

[b]Both constituents are described for the natural oil to occur mainly as *R*-(−)-enantiomers, the ratio between *R*-(−)- and *S*-(+)-stereoisomers not given.

[c]Synonym: *(Z)*-3,7-dimethyl-1,3,6-octatriene.

[d]The values given for the total are the lowest and the highest values of the sum of the components in the individual batches analysed.

The applicant provided a full analysis of the volatile constituents in seven batches obtained by gas chromatography–mass spectrometry (GC–MS).[19] In total, up to 87 peaks were detected in the chromatogram, which were all identified and accounted on average for 96.9% (92.1%–99.7%) of the % GC area. The four compounds indicated in the product specifications account for about 71.3% on average (range 67.8%–77.1%) of % GC area. Besides the four compounds indicated in the product specifications, 13 other compounds were detected at individual levels > 0.5% and are listed in Table 2. These 17 compounds account on average for 91.9% (90.3%–94.3%) of the % GC area. The remaining 70 compounds (ranging

[13]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.

[14]Technical dossier/Supplementary information March 2024/Annex_II_SIn_reply_Lavender_oil_COA_Chrom.

[15]Technical dossier/Supplementary information March 2024/Annex_IIIb_SIn_reply_lavender_oil_ISO_3515_2002.

[16]Technical dossier/Supplementary information March 2024/Annex_IIIa_SIn_reply_lavender_oil _Eur.Ph.07–2010-1338.

[17]Both constituents are described for the natural oil to occur mainly as *R*-(−)-enantiomers which are seen as important markers for quality. Falsifications by adding the *S*-(+)-enantiomers are described and limits for them are defined in the PhEur: *S*-(+)-linalyl acetate: < 1%; *S*-(+)-linalool: < 12%.

[18]Technical dossier/Supplementary information March 2024/Annex V SIn_reply_Lavender_oil_raw_data.

[19]Technical dossier/Supplementary information March 2024/Annex_II_SIn_reply_Lavender_oil_COA_Chrom.

between 0.005% and 0.48%) and accounting on average for 4.7% (1.5%–8.4%) of the % GC area are listed in the footnote.[20] Based on these data, lavender oil is considered a fully defined mixture (EFSA Scientific Committee, 2019a).

TABLE 2 Constituents of lavender oil, accounting for > 0.5% of the composition: batch-to-batch variation based on the analysis of seven batches by gas chromatography–mass spectrometry (GC-MS). The content of each constituent is expressed as the area percent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%.

Constituent EU register name	CAS No	FLAVIS No	% GC area	
			Mean	Range
Linalyl acetate[a]	115-95-7	09.013	39.28	30.91–45.02
Linalool[a]	78-70-6	02.013	27.28	23.17–34.01
4-Terpinenol	562-74-3	02.074	2.00	0.47–4.31
(Z)-β-Ocimene[b]	3338-55-4	01.064	2.70	1.16–3.97
β-Caryophyllene	87-44-5	01.007	6.23	3.22–8.81
β-Farnesene	18794-84-8	01.041	3.07	2.00–4.76
(E)-β-Ocimene[c]	3779-61-1	–	2.36	1.01–3.46
d,l-Borneol	507-70-0	02.016	2.30	1.79–3.02
(R)-(–)-Lavandulol	498-16-8	02.170	1.85	1.82–1.88
Lavandulyl acetate	25905-14-0	09.612	1.76	0.88–3.52
α-Terpineol	98-55-5	02.014	1.24	0.72–1.79
Oct-1-en-3-yl acetate	2442-10-6	09.281	1.02	0.37–1.37
Camphor[d]	76-22-2	–	0.87	0.24–1.50
Octan-3-one	106-68-3	07.062	0.82	0.23–1.45
1,8-Cineole	470-82-6	03.001	0.78	0.33–1.13
Geranyl acetate	105-87-3	09.011	0.56	0.41–0.68
Hexyl butyrate	2639-63-6	09.045	0.50	0.28–0.93
Total			91.90	90.29–94.32[e]

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

[a]Both constituents are described for the natural oil to occur mainly as *R*-(–)-enantiomers, the ratio between *R*-(–)- and *S*-(+)-stereoisomers not given.

[b]Synonym: *(Z)*-3,7-dimethyl-1,3,6-octatriene.

[c]Synonym: *(E)*-3,7-dimethyl-1,3,6-octatriene.

[d]Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given.

[e]The values given for the Total are the lowest and the highest values of the sum of the components in the individual batches analysed.

The applicant performed a literature search (see Section 3.4) for the chemical composition of *L. angustifolia* and its preparations to identify the presence of any recognised substances of concern.[21] Apart from the presence of 1,8 cineole (5.81%) and camphor (13.32%) in the essential oil from the flower of *L. angustifolia*, the EFSA Compendium of botanicals (EFSA, 2012)[22] also reported the presence of α-thujone and β-thujone (not quantified) in an essential oil from the aerial parts of the plant. Thujones were not detected by GC–MS in the essential oil under assessment (limit of detection, LOD 0.001%).

Coumarin was detected and quantified (0.072% and 0.092%) in two batches of the additive under assessment. This substance is listed as a *'substance which shall not be added as such to food''* in the annex III of Regulation EC No 1334/2008.

No other substances of concern were identified in the literature provided by the applicant.

[20]Additional constituents: constituents ($n = 26$) between < 0.5 and ≥ 0.1%: β-caryophyllene epoxide, myrcene, bicyclosesquiphellandrene, hexyl acetate, *trans*-linalool oxide (5-ring), d-limonene, 1-isopropyl-4-methylbenzene (*p*-cymene), neryl acetate, *cis*-linalool oxide (5-ring), octan-3-ol, oct-1-en-3-ol, camphene, 2-(4-methylphenyl) propan-2-ol, *(E)*-α-bergamotene, terpinolene, *d,l*-bornyl formate, hexyl hexanoate, *(Z)*-nerol, 4-isopropylcyclohex-2-en-1-one, butyl butyrate, lavandulyl isovalerate, pin-2(3)-ene (α-pinene), *d,l*-bornyl acetate, 3-octyl acetate, 7-epi-oesquithujene and γ-cadinene; constituents ($n = 17$) between < 0.1 and ≥ 0.05%: *(l)*-α-bisabolol, hexan-1-ol, *(E)*-3,7-dimethylocta-1,5,7-trien-3-ol, 4-isopropylbenzaldehyde, γ-terpinene, hexyl methyl ether, coumarin, *(E,Z)*-1,3,5-undecatriene, pin-2(10)-ene (β-pinene), β-bourbonene, α-thujene, alloaromadendrene, T-muurolol, *(E,Z)*-alloocimene, hexyl 2-methylbutyrate, hexyl tiglate and *trans*-sabinene hydrate; constituents ($n = 27$) between < 0.05 and ≥ 0.005%: β-bisabolene, *(Z)*-α-bergamotene, β-phellandrene, hex-3*(cis)*-en-1-ol, α-terpinene, 4-hydroxy-4-methylpentan-2-one, camphenilone, (–)-*trans*-β-bergamotene, octan-1-ol, 4-methyl-5-hexen-1,4-olide, 4-isopropylbenzyl alcohol, trans-linalool oxide (6-ring), bicyclogermacrene, 4(10)-thujene (sabinene), *l*-carvone, epi-β-santalene, β-sesquiphellandrene, *(E)*-myroxide, 1,1,7-trimethyltricyclo[2.2.1.0.(2.6)]heptane (tricyclene), butyl acetate, norecasantalal, pin-2-en-4-one, α-copaene, *trans*-carveol, β-cubebene, 3,6-dihydro-4-methyl-2-(2-methylprop-1-en-1-yl)-2H-pyran and hex-2*(trans)*-enal.

[21]Technical dossier/Supplementary information March 2024/Literature search_Lavender_oil.

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

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 lavender 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).[23] However, no data supporting this statement were provided.

3.3.3 | Conditions of use

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

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

Animal category	Maximum use level (mg/kg complete feed)
Chickens for fattening	40
Laying hens	40
Turkeys for fattening	40
Piglets	40
Pigs for fattening	40
Sows	40
Veal calves (milk replacers)	40
Cattle for fattening	40
Dairy cows	40
Sheep/goats	40
Horses	40
Rabbits	30
Salmon and other fin fish	40
Dogs	30
Cats	30
Ornamental fish	30
Other species	30

3.4 | Safety

The assessment of the safety of lavender oil is based on the maximum use levels in complete feed proposed by the applicant (Table 3).

No studies to support the safety for target animals, consumers and users were performed with the additive under assessment. The applicant carried out an extensive database search (no time limits) to identify data related to the chemical composition and the safety of preparations obtained from *L. angustifolia*.[24] Four cumulative databases (LIVIVO, NCBI, OVID and ToxInfo), 13 single databases including PubMed and Web of Science and 12 publishers' search facilities including Elsevier, Ingenta, Springer and Wiley were used. The keywords used covered different aspects of safety and the inclusion and exclusion criteria were provided by the applicant.

Many of the individual components of the essential oil have been already assessed as chemically defined flavourings for use in feed and food by the FEEDAP Panel, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) and the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

[23]Technical dossier/Section II.

[24]Technical dossier/Supplementary information March 2024/Literature search_Lavender_oil.

and/or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The flavouring compounds currently authorised for food[25] and/or feed[26] use, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000[27] and the corresponding EFSA opinion are listed in Table 4.

TABLE 4 Flavouring compounds 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 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	Hexan-1-ol	02.005	2013
		Octan-1-ol	02.005	
		Butyl acetate	09.004	
		Hexyl acetate	09.006	
		Butyl butyrate	09.042	
		Hexyl butyrate	09.045	
		Hexyl hexanoate	09.066	
		Hexyl 2-methylbutyrate	09.507	
03	a, ß-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters	*(Z)*-Nerol	02.058	2016a
		Geranyl acetate	09.011	
		Neryl acetate	09.213	
		Hex-2*(trans)*-enal	05.073	2019b
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	2016b
		(R)-(–)-Lavandulol[a]	02.170	2013a, CEF
		Lavandulyl acetate[a]	09.612	
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
		Oct-1-en-3-ol	02.023	2020a
		Oct-1-en-3-yl acetate	09.281	
		3-Octyl acetate[a]	09.254	WHO (2000)
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool[b]	02.013	2012a, 2020b
		α-Terpineol	02.014	2012a
		2-(4-Methylphenyl)propan-2-ol	02.042	
		4-Terpinenol	02.072	
		Linalyl acetate[b]	09.013	
		(I)-α-Bisabolol[a]	02.129	2015a, CEF
		(E)-3,7-Dimethylocta-1,5,7-trien-3-ol[a]	02.146	
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	*d,l*-Borneol	02.016	2016c
		l-Carvone	07.147	
		d,l-Bornyl acetate	09.017	
		d-Camphor[c]	07.215	2016c, 2023c
		4-Isopropylcyclohex-2-en-1-one[a]	07.172	2012a, CEF
		Pin-2-en-4-one[a]	07.196	2011a, CEF; 2012b, CEF
		d,l-Bornyl formate[a]	09.082	2012c, CEF

[25]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.

[26]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.

[27]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
10	Secondary aliphatic saturated or unsaturated alcohols, ketones, ketals and esters with a second secondary or tertiary oxygenated functional group	4-Hydroxy-4-methylpentan-2-one[a]	07.165	2008a, AFC
13	Furanones and tetrahydrofurfuryl derivatives	Linalool oxide[d]	13.140	2012b
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012c, 2021
		Hexyl methyl ether[a]	03.016	2013b, CEF
		3,6-Dihydro-4-methyl-2-(2-methylprop-1-en-1-yl)-2H-pyran[(a)]	13.088	2011b, CEF
23	Benzyl alcohols, aldehydes, acids, esters and acetals	4-Isopropylbenzyl alcohol	02.039	2012d
		4-Isopropylbenzaldehyde	05.022	
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	1-Isopropyl-4-methylbenzene (*p*-cymene)	01.002	2015b
		Terpinolene	01.005	
		α-Terpinene	01.019	
		γ-Terpinene	01.020	
		d-Limonene	01.045	
		Pin-2(10)-ene (β-pinene)	01.003	2016d
		Pin-2(3)-ene (α-pinene)	01.004	
		β-Caryophyllene	01.007	
		Myrcene	01.008	
		Camphene	01.009	
		β-Cubebene[a,e]	01.030	2011c, CEF
		β-Phellandrene[a,e]	01.055	
		1,1,7-Trimethyltricyclo[2.2.1.0.(2.6)] heptane (tricyclene)[a,e]	01.060	
		4(10)-Thujene (sabinene)[a]	01.059	2015b, CEF
		(Z)-3,7-Dimethyl-1,3,6-octatriene (*(Z)*-β-Ocimene)[a]	01.064	
		β-Bourbonene[a]	01.024	
		β-Bisabolene[a]	01.028	
		β-Farnesene[a]	01.041	
32	Epoxides	β-Caryophyllene epoxide[a]	16.043	2014, CEF

*FEEDAP opinion unless otherwise indicated.

[a]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.

[b]Both constituents are described for the natural oil to occur mainly as *R*-(−)-enantiomers, the ratio between *R*-(−)- and *S*-(+)-stereoisomers not given.

[c]Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given. JECFA and EFSA evaluated the enantiomer *d*-camphor (name in the register: *(1R)*-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one [07.215]) for use in food (EFSA, 2008b) and in feed (EFSA FEEDAP Panel, 2016c, 2023c).

[d]Linalool oxide [13.140]: A mixture of *cis*- and trans-linalool oxide (5-ring) was evaluated [13.140] (EFSA FEEDAP Panel, 2012b).

[e]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.

As shown in Table 4, a number of components of lavender oil, accounting on average for about 97% of the % GC peak areas, have been previously assessed and considered safe for use as flavourings. They are currently authorised for use in food[28] without limitations and for use in feed[29] at individual use levels higher than those resulting from the intended use in feed of the essential oil under assessment.

Subsequently, linalool [02.013] was considered safe at 30 mg/kg complete feed for all animal species based on the results of tolerance studies with a mixture of flavourings referred to as 'TuttiFrutti mixture' in chickens for fattening, piglets and cattle for fattening (EFSA FEEDAP Panel, 2020b). The FEEDAP Panel considers that the conclusions reached for linalool can be extrapolated to linalyl acetate [09.013]. Similarly, octan-3-one [07.062] was considered safe at 10 mg/kg complete feed for all animal species based on the results of tolerance studies with a mixture of flavourings referred to as 'MilkyVanilla mixture' in chickens for

[28]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.

[29]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.

fattening, piglets and cattle for fattening (EFSA FEEDAP Panel, 2023b). The FEEDAP Panel considers that the conclusions reached for octan-3-one can be extrapolated to octan-3-ol [02.098] and 3-octyl acetate [09.254] by applying read-across in CG 5.

Camphor (as a mixture of isomers) has not been evaluated for use as a flavouring but is closely related to the flavouring compound *d*-camphor [07.215] already assessed in CG 8 (EFSA FEEDAP Panel, 2016c). Subsequently, *d*-camphor was assessed in tolerance studies with a mixture of flavourings referred to as 'Herbal mixture' in chickens for fattening, piglets, cattle for fattening and salmons. The tolerance studies showed that *d*-camphor was safe up to 5 mg/kg complete feed for all animal species (EFSA FEEDAP Panel, 2023c).

Three compounds, listed in Table 4, β-cubebene [01.030], β-phellandrene [01.055] and tricyclene [01.060] have been evaluated in Flavouring Group Evaluations 25 Revision 2 (FGE.25Rev2) 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, 2011c). In the absence of such toxicological data, the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015b). 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, 2019a).

Twenty-eight volatile compounds have not been previously assessed for use as flavourings. The FEEDAP Panel notes that 21 of them[30] accounting on average for 3.9% of the GC–MS area are aliphatic monoterpenes or sesquiterpenes structurally related to flavourings already assessed in CG 4, 6, 8 and 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-i ntestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted (EFSA FEEDAP Panel, 2012a, 2015b, 2016c, 2016d). *cis*-Linalool oxide (5-ring), *trans*-l inalool oxide (5-ring) and *trans*-l inalool oxide (6-ring) are isomers of linalool oxide [13.140] evaluated in CG 13 (EFSA FEEDAP Panel, 2012b).

Coumarin, as a naturally occurring flavouring substance, was evaluated in 2004 and 2008 by the AFC Panel (EFSA, 2004, 2008c). The safety assessment of coumarin was made by the FEEDAP Panel in the opinion on cassia leaf oil (EFSA FEEDAP Panel, 2022).

The genotoxic potential of three compounds (hexyl tiglate, norecasanatal and *(E)*-myroxide) was predicted with the Organisation for Economic Co-operation and Development (OECD) quantitative structure–activity relationship (QSAR) Toolbox. Structural alerts were identified for all the three compounds.[31] In all cases, predictions of mutagenicity by Ames test (with and without S9 mix) were made by 'read-across' analyses of data available for substances similar to the target compounds (i.e. analogues obtained by categorisation). Categories were defined using general mechanistic and endpoint profilers as well as empirical profilers. Sub-categorisation was performed in order to exclude analogues less similar to the target compounds. For all compounds mutagenicity read-across-based predictions were found negative.[32] On this basis, the alerts raised were discounted.

3.4.1 | Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals made with the essential oil under application 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 using the dose addition assumption within an assessment group, taking into account the relative toxic potency of each component (EFSA Scientific Committee, 2019a).

As the additive under assessment is a fully defined mixture (the identified components represent 97% 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. Linalool, octan-3-one and *d*-camphor, which were included in tolerance studies with mixtures of flavourings 'TuttiFrutti', 'MilkyVanilla' and 'Herbal mixture' (EFSA FEEDAP Panel, 2020b, 2023b, 2023c) 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, and linalyl acetate [09.013] together with linalool [02.013].

Linalool and linalyl acetate, octan-3-one and related compounds (octan-3-ol and 3-octyl acetate), and camphor

For linalool [02.013] the applicant provided evidence in the form of tolerance trials in chickens for fattening, piglets and cattle for fattening, which showed that linalool was safe up to 30 mg/kg complete feed for all animal species with a margin

[30]Lavandulyl isovalerate (CG 4); *trans*-sabinene hydrate, T-muurolol (CG 6); *trans*-carveol, camphenilone, camphor (CG 8); *trans*-3,7-dimethyl-1,3,6-octatriene, *(E,Z)*-alloocimene, *(E,Z)*-1,3,5-undecatriene, β-sesquiphellandrene, α-thujene, α-copaene, 7-epi-sesquithujene, *(Z)*-α-bergamotene, *(E)*-α-bergamotene, alloaromadendrene, epi-β-santalene, (–)-*trans*-β-bergamotene, bicyclosesquiphellandrene, bicyclogermacrene and γ-cadinene (CG 31).

[31]Structural alerts were identified were due to the presence of: (i) an ester group for hexyl tiglate, (ii) an aldehyde group for (norecasanatal; (iii) an epoxide for *(E)*-myroxide.

[32]Technical dossier/Supplementary information March 2024/Annex VII_SIn_reply_Lavender_oil_QSAR.

of safety of 10 (EFSA FEEDAP Panel, 2020b). The highest concentration in feed of the sum of linalool and linalyl acetate resulting from the use of the additive would be 30 mg/kg complete feed, which is considered safe for the target species.[33]

For octan-3-one [07.062] the results of tolerance trials in chickens for fattening, piglets and cattle for fattening indicated that the compound was safe up to 10 mg/kg complete feed for all animal species with a margin of safety of 10 (EFSA FEEDAP Panel, 2023b). The FEEDAP Panel considers that the conclusions reached for octan-3-one can be extrapolated to octan-3-ol [02.098] and 3-octyl acetate [09.254] by applying read-across. The highest concentration in feed of the sum of octan-3-one, octan-3-ol and 3-octyl acetate resulting from the use of the additive would be 0.84 mg/kg complete feed, which is considered safe for the target species.[34]

Similarly, for *d*-camphor [07.215] the tolerance trials in chickens for fattening, piglets, cattle for fattening and salmons showed that *d*-camphor was safe up to 5 mg/kg complete feed for all animal species with a margin of safety of 10 (EFSA FEEDAP Panel, 2023c). The FEEDAP Panel considers that the conclusions reached for *d*-camphor can be extrapolated to *l*-camphor by applying read-across. The highest concentration in feed of camphor resulting from the use of the additive would be 0.6 mg/kg complete feed, which is considered safe for the target species.[35]

Components other than linalool, linalyl acetate, octan-3-one and related compounds, and camphor

Based on considerations related to structural and metabolic similarities, the components were allocated to ten assessment groups, corresponding to the chemical groups (CGs) 1, 3, 4, 5, 6, 7, 8, 10, 13, 16, 23, 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, 2015b, 2015c). The allocation of the components to the (sub-)assessment groups is shown in Table 5 and in the corresponding footnote.

For each component in the assessment group, exposure in target animals was estimated considering the use levels in feed, the percentage of the component in the oil and the default values for feed intake according to the guidance on the safety of feed additives for target species (EFSA FEEDAP Panel, 2017b). Default values on body weight (bw) are used to express exposure in terms of mg/kg bw per day. The intake levels of the individual components are calculated for chickens for fattening, the species with the highest ratio of feed intake/body weight per day, are shown in Table 5.

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[36]). For some components in the assessment group, toxicological data were available to derive no observed adverse effect levels (NOAEL) values. Structural and metabolic similarity among the components in the assessment groups were evaluated to explore the application of read-across. If justified, extrapolation can be made from a known NOAEL of a component in an assessment group to the other components of the group with no available NOAEL. If sufficient evidence is available for the components of a (sub)assessment group, a (sub) assessment group NOAEL can be derived.

Toxicological data from sub-chronic studies, from which NOAEL values could be derived, were available for several compounds in CG 1 (EFSA FEEDAP Panel, 2013), for the representative compound citral [05.020] and for hex-2(*trans*)-enal [05.073] in CG 3 (EFSA FEEDAP Panel, 2019, 2016a), for the representative compound citronellol [02.011] and for hex-3(*cis*)-en-1-ol [02.056] in CG 4 (EFSA FEEDAP Panel, 2016b), oct-1-en-3-ol [02.023] in CG 5 (EFSA FEEDAP Panel, 2020a), terpineol [02.230][37] in CG 6 (EFSA FEEDAP Panel, 2012a), *d,l*-isobornyl acetate [09.218] in CG 8 (EFSA FEEDAP Panel, 2016c), 1,8-cineole [03.001] in CG 16 (EFSA FEEDAP Panel, 2012c, 2021), myrcene [01.008], *d*-limonene [01.045] and β-caryophyllene [01.007] in CG 31 (EFSA FEEDAP, 2015b, 2016d) and β-caryophyllene epoxide [16.043] for CG 32 (EFSA CEF Panel, 2014). In addition, for benzyl alcohol the EFSA Panel on Food Additives and Flavourings (FAF) established an acceptable daily intake (ADI) of 4 mg/kg bw per day based on a NOAEL of 400 mg/kg bw per day from a carcinogenicity study in rats (EFSA FAF Panel, 2019).

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 (Araujo et al., 1996; also reported in ECHA, 2018). An uncertainty factor (UF) of 2 was applied to the NOAEL of 60 mg/kg bw per day to take into account the nature of the study.

For CG 1, a group NOAEL of 120 mg/kg per day was derived from the toxicological data available and was used as a group NOAEL for all the compounds belonging to CG 1.

The NOAEL of 345 mg/kg bw per day for citral [05.020] was extrapolated to *(Z)*-nerol [02.058], geranyl acetate [09.011] and neryl acetate [09.213] belonging to CG 3. Considering the structural and metabolic similarity of geranyl and lavandulyl derivatives, the NOAEL of citral [05.020] was also applied to *(R)*-(−)-lavandulol [02.170], lavandulyl acetate [09.612] and lavandulyl isovalerate in CG 4. For these compounds, an uncertainty factor (UF) of 2 was applied to the NOAEL of 345 mg/kg to take into account the uncertainty in read-across.

[33]Calculated considering the maximum proposed use level of 40 mg/kg complete feed and the highest concentration of the sum of linalool and linalyl acetate (75.4%) in the seven batches.

[34]Calculated considering the maximum proposed use level of 40 mg/kg complete feed and the highest analysed concentrations of octan-3-one (1.45%), octan-3-ol (0.49%) and 3-octyl acetate (0.16%) in the seven batches.

[35]Calculated considering the maximum proposed use level of 40 mg/kg complete feed and the highest analysed concentrations of camphor (1.5%) in the seven batches.

[36]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/.

[37]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.

For the subgroup of terpinyl derivatives in CG 6, i.e. α-terpineol [02.072] and 4-terpinenol [02.072], and for α-bisabolol [02.129] and T-muurolol the reference point was selected based on the NOAEL of 250 mg/kg bw per day available for terpineol [02.230]. A UF of 2 was applied to the NOAEL of 250 mg/kg bw per day to take into account the short duration (35 days) of the study with terpineol (EFSA FEEDAP Panel, 2012a).

For *d,l*-borneol [02.016] and *d,l*-bornyl acetate [09.218] in CG 8, a NOAEL of 15 mg/kg bw per day was taken from a study with *d,l*-isobornyl acetate [09.218]. Read-across was applied using the NOAEL of 400 mg/kg bw per day for benzyl alcohol [02.010] to extrapolate to isopropylbenzylaldehyde [05.022] and isopropylbenzyl alcohol [02.039] in CG 23.

The NOAELs of 44, 250 and 222 mg/kg bw per day for the representative compounds of CG 31, myrcene [01.008], limonene [01.001] and β-caryophyllene [01.007] were applied, respectively, using read-across to the compounds within sub-assessment groups II (β-farnesene *cis*-3,7-dimethyl-1,3,6-octatriene and, *trans*-3,7-dimethyl-1,3,6-octatriene), III (terpinolene [01.055], γ-terpinene [01.020], β-bisabolene [01.028], β-phellandrene [01.055] and β-sesquiphellandrene) and V (bicyclosesquiphellandrene, camphene [01.009], *(E)*-α-bergamotene, γ-cadinene, α-pinene [01.004], α-thujene, β-pinene [01.003], β-bourbonene [01.024], alloaromadendrene, *(Z)*-α-bergamotene, bicyclogermacrene, sabinene [01.059], (–)-*(E)*-β-bergamotene, tricyclene [01.060], epi-β-santalene, α-copaene and β-cubebene [01.030]),[38] respectively (EFSA CEF Panel, 2015b, 2015c). Read-across was applied from myrcene to *(E)*-3,7-dimethylocta-1,5,7-trien-3-ol [02.146] in CG 6 and from β-caryophyllene to *trans*-sabinene hydrate in CG 6.

For coumarin, the reference point of 10 mg/kg bw per day used to derive the tolerable daily intake (TDI) as food flavouring was selected (EFSA, 2008c).

For the remaining compounds,[39] toxicity studies performed with the compounds under assessment and NOAEL values derived from toxicity studies were not available and read-across was not possible. Therefore, the threshold of toxicological concern (TTC) approach was applied (EFSA FEEDAP Panel, 2017b; EFSA Scientific Committee, 2019c).

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 risk characterisation, the margin of exposure (MOE) was calculated for each component as the ratio between the reference point and the exposure. For each assessment group, the combined (total) margin of exposure (MOET) was calculated as the reciprocal of the sum of the reciprocals of the MOE of the individual substances (EFSA Scientific Committee, 2019a). A MOET > 100 allowed for interspecies- and intra-individual variability (as in the default 10 × 10 uncertainty factor). 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.[40]

The approach to the safety assessment of lavender oil for the target species is summarised in Table 5. The calculations were done for chickens for fattening, the species with the highest ratio of feed intake/body weight and represent the worst-case scenario at the use level of 40 mg/kg complete feed.

TABLE 5 Compositional data, intake values (calculated for chickens for fattening at 40 mg/kg complete feed), reference points, margin of exposure (MOE) for the individual components of lavender 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 conc. In the oil	Highest feed conc.	Daily intake[a]	Cramer class[b]	NOAEL[c]	MOE[d]	MOET[e]
Constituent	–	%	mg/kg	mg/kg bw/day	–	mg/kg bw/day	–	–
CG 1								
Hexyl acetate	09.006	0.94	0.378	0.0339	(I)	120	3540	
Hexyl butyrate	09.045	0.93	0.373	0.0335	(I)	120	3582	
Hexyl hexanoate	09.066	0.30	0.122	0.0109	(I)	120	10,981	
Butyl butyrate	09.042	0.18	0.073	0.0066	(I)	120	18,261	
Hexan-1-ol	02.005	0.15	0.058	0.0052	(I)	120	22,889	
Hexyl tiglate	09.887	0.07	0.028	0.0025	(I)	120	47,067	

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

[39]CC I (3 mg/kg bw per day): 2-(4-methylphenyl)propan-2-ol, *trans*-carveol, 4-hydroxy-4-methylpentan-2-one, hexyl methyl ether, *(E,Z)*-1,3,5-undecatriene, *(E,Z)*-alloocimene, 7-epi-sesquithujene; CC II (0.91 mg/kg bw per day): 4-isopropylcyclohex-2-en-1-one, camphenilone, pin-2-en-4-one, *cis*-linalool oxide (5-ring), *trans*-linalool oxide (5-ring), *trans*-linalool oxide (6-ring), 3,6-dihydro-4-methyl-2-(2-methylprop-1-en-1-yl)-2H-pyran; CC III (0.15 mg/kg bw per day): norecasantalal, 4-methyl-5-hexen-1,4-olide, *(E)*-myroxide.

[40]Compounds included in the assessment groups but not reported in the table: octan-1-ol and butyl acetate (CG 1); *(Z)*-nerol and hex-2*(trans)*enal, (CG 3); hex-3(*cis*)-en-1-ol (CG 4); *trans*-sabinene hydrate (CG 6); 4-isopropylbenzaldehyde and 4-isopropylbenzyl alcohol (CG 23); α-terpinene β-bisabolene, β-phellandrene and β-sesquiphellandrene (CG 31, III); α-thujene, β-pinene [01.003], β-bourbonene [01.024], alloaromadendrene, *(Z)*-α-bergamotene, bicyclogermacrene, sabinene [01.059], (–)-*(E)*-β-bergamotene, tricyclene [01.060], epi-β-santalene, α-copaene, β-cubebene [01.030].

TABLE 5 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS-No**	**Highest conc. In the oil**	**Highest feed conc.**	**Daily intake[a]**	**Cramer class[b]**	**NOAEL[c]**	**MOE[d]**	**MOET[e]**
Hexyl 2-methylbutyrate	09.507	0.07	0.027	0.0024	(I)	120	49,877	
								1262
CG 3								
Geranyl acetate	09.011	0.68	0.272	0.0244	(I)	345	14,129	
Neryl acetate	09.213	0.35	0.139	0.0125	(I)	345	27,688	
								9355
CG 4								
Lavandulyl acetate	09.612	3.52	1.408	0.1264	(I)	172.5	1364	
(R)-(–)-Lavandulol	02.170	1.88	0.751	0.0674	(I)	172.5	2559	
Lavandulyl isovalerate		0.19	0.076	0.0069	(I)	172.5	25,151	
								860
CG 5								
Oct-1-en-3-yl-acetate	09.281	1.37	0.549	0.0493	(I)	6.7	136	
Oct-1-en-3-ol	02.023	0.45	0.179	0.0161	(I)	6.7	417	
MOET CG 5								102
CG 6								
4-Terpinenol	02.072	4.31	1.723	0.1547	(I)	125[(f)]	808	
α-Terpineol	02.014	1.79	0.715	0.0642	(I)	125[(f)]	1947	
2-(4-Methylphenyl)propan-2-ol	02.042	0.34	0.134	0.0121	I	*3*	249	
(I)-α-Bisabolol	–	0.14	0.056	0.0050	(III)	125[(f)]	24,864	
(E)-3,7-Dimethylocta-1,5,7-trien-3-ol	02.146	0.09	0.037	0.0033	(II)	44	13,175	
T-Muurolol	–	0.09	0.037	0.0033	(I)	125[(f)]	37,430	
MOET CG 6								170
CG 7								
Norecasantalan	–	0.02	0.007	0.0007	III	*0.15*	232	
CG 8								
d,l-Borneol	02.016	3.02	1.208	0.1085	(I)	15	138	
d,l-Bornyl formate	09.082	0.28	0.113	0.0102	(I)	15	1476	
4-Isopropylcyclohex-2-en-1-one	07.172	0.21	0.082	0.0074	II	0.91	123	
d,l-Bornyl acetate	09.218	0.21	0.062	0.0056	(I)	15	2678	
l-Carvone	07.147	0.16	0.014	0.0013	II	*0.91*	47,740	
Camphenilone	–	0.04	0.014	0.0012	(II)	60	745	
Pin-2-en-4-one	07.196	0.03	0.007	0.0006	II	*0.91*	1408	
trans-Carveol	–	0.02	0.007	0.0006	I	*3*	4914	
MOET CG 8								54
CG 10								
4-Hydroxy-4-methylpentan-2-one	07.165	0.04	0.015	0.0013	I	*3*	2258	
CG 13								
cis-Linalool oxide (5-ring)	–	0.48	0.192	0.0173	II	*0.91*	53	
trans-Linalool oxide (5-ring)	–	0.45	0.178	0.0160	II	*0.91*	57	
trans-Linalool oxide (6-ring)	–	0.03	0.012	0.0011	II	*0.91*	817	
4-Methyl-5-hexen-1,4-olide	–	0.03	0.012	0.0010	III	*0.15*	144	
								22

(Continues)

TABLE 5 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS-No**	**Highest conc. In the oil**	**Highest feed conc.**	**Daily intake[a]**	**Cramer class[b]**	**NOAEL[c]**	**MOE[d]**	**MOET[e]**
CG 16								
1,8-Cineole	03.001	1.13	0.452	0.0406	(II)	**100**	2464	
Hexyl methyl ether	03.016	0.16	0.066	0.0059	I	*3*	509	
3,6-Dihydro-4-methyl-2-(2-methylprop-1-en-1-yl)-2H-pyran	13.088	0.01	0.003	0.0003	II	*0.91*	3620	
								378
CG 31, II (Acyclic alkanes)								
β-Farnesene	01.041	4.76	1.902	0.1708	(I)	44	258	
(Z)-β-Ocimene	01.064	3.97	1.589	0.1426	(I)	44	308	
(E)-β-Ocimene	–	3.46	1.384	0.1242	(I)	44	354	
Myrcene	01.008	0.61	0.242	0.0218	(I)	**44**	2022	
(E,Z)-1,3,5-Undecatriene	–	0.11	0.044	0.0039	I	*3*	766	
(E,Z)-Allocimene	–	0.08	0.032	0.0029	I	3	1031	
MOET CG 31, II								79
CG 31, III (Cyclohexene hydrocarbons)								
d-Limonene	01.045	0.97	0.390	0.0350	(I)	**250**	7148	
Terpinolene	01.005	0.24	0.095	0.0085	(I)	250	29,376	
γ-Terpinene	01.020	0.16	0.064	0.0058	(I)	250	43,242	
α-Terpinene	01.019	0.05	0.021	0.0019	(I)	30[(g)]	16,066	
								3856
CG 31, IV (Benzene hydrocarbons, alkyl)								
p-Cymene	01.002	0.52	0.210	0.0188	I	**154**	8184	
CG 31, V (Bi-, tricyclic, non-aromatic hydrocarbons)								
β-Caryophyllene	01.007	8.81	3.522	0.3162	(I)	**222**	702	
Bicyclosesquiphellandrene	–	0.60	0.242	0.0217	(I)	222	10,236	
Camphene	01.009	0.36	0.143	0.0128	(I)	222	17,315	
(E)-α-Bergamotene	–	0.27	0.110	0.0098	(I)	222	22,563	
γ-Cadinene	–	0.15	0.058	0.0052	(I)	222	42,344	
α-Pinene	01.004	0.21	0.085	0.0076	(I)	222	29,162	
7-epi-Sesquithujene	–	0.15	0.059	0.0053	I	*3*	568	
MOET CG 31, V								291
CG 32								
β-Caryophyllene epoxide	16.043	0.71	0.284	0.0255	(III)	**109**	4281	
(E)-Myroxide	–	0.02	0.008	0.0008	III	*0.15*	199	
MOET CG 32								190
Coumarin	–	0.09	0.037	0.0033	(III)	**10**	3027	

[a]Intake calculations for the individual components are based on the use level of 40 mg/kg in feed for chickens for fattening, the species with the highest ratio of feed intake/body weight.

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

[c]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.

[d]The MOE for each component is calculated as the ratio of the reference point (no observed adverse effect level, NOAEL) to the intake.

[e]The combined margin of exposure (MOET) is calculated for each assessment group as the reciprocal of the sum of the reciprocals of the MOE of the individual substances.

[f]An uncertainty factor of 2 was applied to the NOAEL of 250 mg/kg bw per day for terpineol (short duration of the study).

[g]An uncertainty factor of 2 was applied to the NOAEL of 60 mg/kg bw per day for α-terpinene (nature of the study).

From the lowest MOET of 22 for chickens for fattening, the MOET for CG 13 was calculated for the other target species considering the respective daily feed intake/kg bw and conditions of use. The results are summarised in Table 6.

TABLE 6 Combined margin of exposure (MOET) for the assessment group CG 13 calculated for the different target animal categories at the proposed use levels in feed and maximum safe use levels in feed to ensure a MOET ≥ 100.

Animal category	Daily feed intake (g DM/kg bw)	Proposed use level (mg/kg complete feed)[a]	Lowest MOET CG 13	Maximum safe use level (mg/kg complete feed)[a]
Chickens for fattening	79	40	22	9
Laying hens	53	40	33	13
Turkeys for fattening	59	40	29	12
Piglets	44	40	40	16
Pigs for fattening	37	40	47	19
Sows lactating	30	40	58	23
Veal calves (milk replacer)	19	40	98	39
Cattle for fattening	20	40	87	35
Dairy cows	31	40	56	22
Sheep/goats	20	40	87	35
Horses	20	40	87	35
Rabbits	50	30	46	14
Salmonids	18	40	97	39
Dogs	17	30	136	–[b]
Cats[c]	20	30	116	7
Ornamental fish	5	30	463	–

[a]Complete feed containing 88% dry matter (DM), milk replacer 94.5% DM.

[b]For the species for which the MOET is > 100, the proposed use level is considered safe.

[c]The MOET for cats is increased to 500 because of the reduced capacity of glucuronidation.

Table 6 shows that for dogs and ornamental fish the MOET exceeds the value of 100, under the proposed conditions of use in complete feed. For the other species, the maximum safe use levels in feed were calculated to ensure a MOET ≥ 100. Because glucuronidation is an important metabolic reaction to facilitate the excretion of the components of the essential oil and considering that cats have an unusually low capacity for glucuronidation, particularly of aromatic compounds (Court & Greenblatt, 1997; Lautz et al., 2021), the use of lavender oil as an additive in cat feed needs a wider margin of exposure. A MOET of 500 is considered adequate. For dogs and ornamental fish, lavender oil is considered safe at the proposed use level in feed of 30 mg/kg complete feed. For the other species, the resulting maximum safe levels in feed are shown in Table 6. These levels are extrapolated to physiologically-related minor species. For the other species not considered, the lowest value of 7 mg/kg complete feed is applied.

Use in water for drinking

No specific proposals have been made by the applicant for the use level in water for drinking. The FEEDAP Panel considers that the use 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.

3.4.1.1 | *Conclusions on safety for the target species*

The FEEDAP Panel considers that the levels of lavender oil summarised in Table 7 are safe for the respective target species.

TABLE 7 Safe concentrations of lavender oil in complete feed (mg/kg) for all animal species and categories.

Animal categories	Safe concentration (mg/kg complete feed)[a]
Turkeys for fattening	12
Chickens for fattening, other poultry for fattening or reared for laying/reproduction and ornamental birds	9
Laying hens and other laying/reproductive birds	13
Pigs for fattening	19
Piglets and other porcine species for meat production or reared for reproduction	16
Sows and other porcine species for reproduction	23
Veal calves (milk replacer)	39
Sheep/goats	35
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction, cervids and camelids at the same physiological stage	35
Dairy cows and other ruminants, cervids and camelids for milk production or reproduction	22
Horses and other equines	35
Rabbits and other leporids	14
Salmonids and minor fin fish	39
Dogs	30
Cats	7
Ornamental fish	30
Other species	7

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

The FEEDAP Panel considers that the use level 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

Lavender oil is added to a wide range of food categories for flavouring purposes. Although individual consumption figures are not available, the Fenaroli's handbook of flavour ingredients (Burdock, 2009) cites values of 0.00008 mg/kg bw per day for lavender oil (FEMA 2622). Fenaroli also reports use levels in food and beverages in the range of 2 mg/kg up to 11 mg/kg for lavender oil. The estimated human intake from the FEMA evaluation for lavender oil is 810 μg/person per day (Fukushima et al., 2020).

Most of the individual constituents of the essential oil under assessment are currently authorised as food flavourings without limitations and have been already 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 lavender oil are expected to be extensively metabolised and excreted in the target species. For the major components, linalyl acetate and linalool, the available data in laboratory animals and humans indicate that they are absorbed, metabolised by oxidation and excreted and are not expected to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2012a). Consequently, relevant residues in food products are unlikely.

Considering the above and the reported human exposure due to the direct use of lavender oil in food (Burdock, 2009), it is unlikely that the consumption of products from animals given lavender oil at the proposed maximum use level would substantially increase human background exposure. The use of lavender oil in animal nutrition under the proposed conditions of use is safe for human consumers of animal products.

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 made a literature search aimed at retrieving studies related to the safety of preparations obtained from *L. angustifolia* for users.[41] None of the references retrieved were considered relevant to the safety assessment.

[41]Technical dossier/Supplementary information March 2024/Literature search_lavender oil.

The applicant provided a safety data sheet[42] for lavender oil, which identified concerns for dermal and eye irritation and dermal and respiratory sensitisation.

The FEEDAP Panel concludes that lavender oil should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser.

3.4.4 | Safety for the environment

L. angustifolia is a species native to Europe where it is also cultivated for commercial purposes.

The use of lavender oil in animal feed under the proposed conditions of use is not expected to pose a risk to the environment.

3.5 | Efficacy

The flowering tops of lavender (*L. angustifolia* Mill.) and their oil are listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by FEMA with the reference numbers 2619 and 2622.

Since lavender 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

The conclusions of the FEEDAP Panel on the safe levels in complete feed of lavender oil from the fresh flowering tops of *L. angustifolia* Mill. for all animal species are summarised as follows:

Animal categories	Safe concentration (mg/kg complete feed)[a]
Turkeys for fattening	12
Chickens for fattening, other poultry for fattening or reared for laying/reproduction and ornamental birds	9
Laying hens and other laying/reproductive birds	13
Pigs for fattening	19
Piglets and other porcine species for meat production or reared for reproduction	16
Sows and other porcine species for reproduction	23
Veal calves (milk replacer)	39
Sheep/goats	35
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction, cervids and camelids at the same physiological stage	35
Dairy cows and other ruminants, cervids and camelids for milk production or reproduction	22
Horses and other equines	35
Rabbits and other leporids	14
Salmonids and minor fin fish	39
Dogs	30
Cats	7
Ornamental fish	30
Other species	7

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

The FEEDAP Panel considers that the use level 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 lavender oil 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 irritant to skin and eyes, and as a dermal and respiratory sensitiser.

Since the oil of the flowering tops of *L. angustifolia* Mill. 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.

[42]Technical dossier/Supplementary information March 2024/Annex VIII_SIn_reply_lavender_oil_MSDS. Aspiration hazard (H304, Category 1), Hazard for skin corrosion/irritation (H315, Category 2), Serious eye damage/eye irritation (H319, Category 2), Skin sensitisation (H317, Category 1), in accordance with the criteria outlined in Annex I of 1272/2008/EC (CLP/EU-GHS).

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
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
14/03/2024	Reception of supplementary information from the applicant (partial dataset: lavender oil) - Scientific assessment remains suspended
22/05/2024	The application was split and a new EFSA-Q-2024-00306 was assigned to the preparation included in the present assessment
08/07/2024	Partial withdrawal of the application for the following additives: lilac chastetree extract and savoury summer tincture
26/08/2024	Reception of a partial evaluation report of the European Union Reference Laboratory for Feed Additives. Scientific assessment re-started for the additives included in the partial report: 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)
17/09/2024	Opinion adopted by the FEEDAP Panel on lavender oil (EFSA-Q-2024-00306). 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

AFC	EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
bw	body weight
BDG	botanically defined group
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
EINECS	European Inventory of Existing Chemical Substances
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
FLAVIS No	FLAVIS number
GC	gas chromatography
GC–MS	gas chromatography–mass spectrometry
GC-FID	gas chromatography–flame ionisation detection
ISO	International Organization for Standardization

JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
MOE	margin of exposure
MOET	total margin of exposure
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCBs	polychlorinated biphenyls
PhEur	European Pharmacopoeia
QSAR	quantitative structure activity relationship
TTC	threshold of toxicological concern
UF	uncertainty factor
WHO	World Health Organization

ACKNOWLEDGEMENTS

The Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Jaume Galobart and Maria Vittoria Vettori.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2010-01307 (New EFSA-Q-2024-00306)

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PANEL MEMBERS

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Ilen Röhe, Katerina Theodoridou

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How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Villa, R. E., Azimonti, G., Bonos, E., Christensen, H., Durjava, M., Dusemund, B., Gehring, R., Glandorf, B., Kouba, M., López-Alonso, M., Marcon, F., Nebbia, C., Pechová, A., Prieto-Maradona, M., Röhe, I., Theodoridou, K., Bastos, M. d. L., Brantom, P., … Manini, P. (2024). Safety and efficacy of a feed additive consisting of an essential oil derived from the flowering tops of *Lavandula angustifolia* Mill. (lavender oil) for use in all animal species (FEFANA asbl). *EFSA Journal*, *22*(10), e9017. https://doi.org/10.2903/j.efsa.2024.9017