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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of a tincture derived from the leaves of *Salvia officinalis* L. (sage tincture) 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 | Emilio Benfenati | 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://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 a tincture from the leaves of *Salvia officinalis* L. (sage tincture) when used as a sensory additive in feed and in water for drinking for all animal species. The product is a [redacted] solution, with a dry matter content of approximately 1.76%. The product contains on average 0.314% (w/w) total polyphenols (of which 0.0458% are flavonoids). Estragole was not detected in the tincture. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the use of sage tincture is safe at the proposed use level of 500 mg/kg complete feed for ornamental fish. For the other species the calculated safe concentrations in complete feed are: 35 mg/kg for chickens for fattening, 52 mg/kg for laying hens, 47 mg/kg for turkeys for fattening, 75 mg/kg for pigs for fattening, 62 mg/kg for piglets, 91 mg/kg for sows, 156 mg/kg for veal calves, 137 mg/kg for cattle for fattening, sheep/goats and horses, 89 mg/kg for dairy cows, 55 mg/kg for rabbits, 156 mg/kg for salmonids, 164 mg/kg for dogs and 137 mg/kg for cats. These conclusions were extrapolated to other physiologically related species. For any other species, the additive is safe at 35 mg/kg complete feed. No safety concerns were identified for the consumer and the environment from the use of the additive in animal feed. Regarding user safety, the additive under assessment should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. Any exposure is considered a risk. Since the leaves of *S. officinalis* are recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy was necessary.

KEYWORDS

1,8-cineole, camphor, flavouring compounds, rosmarinic acid, sage tincture, *Salvia officinalis* L., sensory additives, thujones

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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 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 7 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, savory summer oil, savory 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 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: sage tincture from *Salvia officinalis* L.[5] for use in all animal species.

The remaining 28 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 (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). EFSA received directly from the applicant the technical dossier in support of this application. 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 sage tincture from the leaves of *S. officinalis*, when used under the proposed conditions of use (see **Section 3.3.3**).

1.2 | Additional information

Sage tincture from *S. officinalis* 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[6] in support of the authorisation request for the use of sage tincture from *S. officinalis* as a feed additive. The dossier was received on 26 May 2025 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2025-00328.[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); devils claw extract (wb), balm leaves extract (sb), olive extract (sb) (16 December 2024).

[4]Register of feed additives, Annex II, withdrawn by OJ L162, 10.5.2021, p. 5.

[5]Accepted name: *Salvia officinalis* L.

[6]Dossier reference: FAD-2010-0137.

[7]The original application EFSA-Q-2010-01307 was split on 26/05/2025 and a new EFSA-Q-2025-00328 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.

Several components of the tincture 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 preparations 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. During the assessment, upon request of EFSA, the EURL issued two partial reports.[9] The additive under assessment is included in the second partial report. In particular, for the characterisation of sage tincture the EURL recommended methods based on (i) spectrophotometry for the determination of total polyphenols and total flavonoids; (ii) gas chromatography coupled with flame ionisation detection (GC-FID) for the determination of thujones, camphor and 1,8-cineole; (iii) high-performance liquid chromatography (HPLC) for the quantification of the phytochemical marker rosmarinic acid in sage tincture; and (iv) high-performance thin layer chromatography (HPTLC) profile for the unequivocal identification of sage tincture.[10]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of sage tincture from *S. officinalis* 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 naturally occurring substances of potential concern for human and animal health,[12] Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012a), 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 efficacy of feed additives (EFSA FEEDAP Panel, 2024), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023), 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, sage tincture, is obtained from the dried leaves of *Salvia officinalis* 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

S. officinalis L. is a small perennial shrub belonging to the family Lamiaceae. It is characterised by its grey-green leaves and its lavender-like flower borne on short spikes. The species is native to the northern parts of the Mediterranean but has been introduced into many other temperate regions of the world. It is referred to as the common sage (sometimes the garden sage) to distinguish it from other *Salvia* species carrying the same name (e.g. Spanish sage, *Salvia officinalis* subsp. *lavandulifolia* (Vahl) Gams; Clary sage, *Salvia sclarea* L.). In common with other sage plants, it has a long history of use as a culinary herb.

The tincture is produced from the dried leaves by extended extraction for [redacted] under ambient conditions with a [redacted] solvent mixture ([redacted]. The tincture is recovered by pressing to separate solid and liquid phases and the solution obtained is then clarified by filtration.

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

[9]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.

[10]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.

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

3.2 | Uses other than feed flavourings

While there is no specific EU authorisation for any *S. officinalis* 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'.

'Sage leaf (*Salvia officinalis* L. folium)' is described in a monograph of the European Pharmacopoeia 11.5 (PhEur, 2024) and '*Salvia officinalis* L., folium and *Salvia officinalis* L., aetheroleum' in monographs of the European Medicines Agency (EMA, 2016a, 2016b) for medicinal uses.

3.3 | Characterisation

3.3.1 | Characterisation of sage tincture

Sage tincture is a brown liquid, with a characteristic odour (characteristic of aromatic plant, phenolic and camphor odour). It has an average density of [redacted] kg/m^3 ([redacted] kg/m^3) and a pH of [redacted] ([redacted]).[14] No Chemical Abstract Service (CAS) number or European Community (EC) number is specifically associated to sage tincture.[15] The Council of Europe (CoE) number 414 is associated to *S. officinalis* L.

Table 1 summarises the results of the proximate analysis of five batches of the additive.[16] The solvent represents on average 98.24% of the additive leaving a dry matter (DM) content of 1.76%. The DM consists of inorganic material measured as ash (10.2%) and a plant-derived organic fraction of 89.8%, which includes proteins, lipids and reducing sugars (after hydrolysis). The unidentified organic fraction remaining after subtracting the values for proteins, lipids and reducing sugars, contains a variety of non-volatile secondary metabolites including phenolic compounds (see Table 2).

TABLE 1 Proximate analysis of a sage tincture based on the analysis of five batches.

Constituent	Mean % (w/w)	Range % (w/w)
Dry matter	1.76	1.75–1.78
Ash	0.18	0.16–0.20
Organic fraction	1.58	1.56–1.61
Proteins	< 0.08	< 0.08
Lipids	0.07	0.06–0.08
Reducing sugars[1]	0.42	0.40–0.50
'Unidentified'[2]	1.43	1.40–1.45
Solvent	98.24	98.22–98.25

[1]After hydrolysis, expressed as glucose equivalents.

[2]'Unidentified' (by difference) calculated subtracting ash, proteins, lipids and sugar from the dry matter. It includes non-volatile secondary plant metabolites.

The fraction of secondary metabolites was characterised in the same five batches of sage tincture and the results are summarised in Table 2. The tincture was shown to contain polyphenols (0.314% on average, w/w) determined by spectrophotometry (at 760 nm) and expressed as gallic acid equivalents (GAE).[17] The FEEDAP Panel notes that the polyphenols were determined by the Folin–Ciocalteu method, which is a widely used method for the determination of total content of polyphenols in plant extracts, but which does not give the true concentrations of polyphenols of different types. This may lead to an overestimation of their concentrations in comparison to results obtained by HPLC depending on the substances of interest and the standard used (Everette et al., 2010; Samara et al., 2022). The concentration of flavonoids (0.046% on average, w/w, expressed as quercetin equivalents) was determined by spectrophotometry (at 415 nm). Eleven unidentified

[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 April 2024/Annex_II_4_Results of analysis.

[15]The following entries were found at https://echa.europa.eu home: 'Sage, Salvia officinalis, ext. (Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Salvia officinalis, Labiatae.)', CAS number 84082-79-1, EC number 282-025-9.

[16]Technical dossier/Supplementary information April 2024/Section II_Identity and Annex_II_4_Results of analysis.

[17]Technical dossier/Supplementary information April 2024/Section_II_Identity and Annex_II_4_Results of analysis.

polyphenols (phenolic acids, flavones and flavonols) were detected by HPTLC and also expressed as GAE.[18] Hydroxycinnamic acid derivatives and luteolin were quantified by HPLC with ultraviolet (UV) detection[19] and volatile compounds by GC-FID[20] in the same five batches of the tincture. Estragole was below the limit of detection (LOD, 4.69 mg/L, corresponding to less than 0.0005%) in all batches.

TABLE 2 Concentrations of secondary metabolites in sage tincture based on the analysis of five batches (mean and range).

				Mean	Range
Constituent	**CAS no**	**FLAVIS no**	**Method**	**% (w/w)**	**% (w/w)**
Total polyphenols[1]	–	–	Folin–Ciocalteu[2]	0.314	0.295–0.328
Flavonoids			Spectrophotometry[3]	0.0458	0.0444–0.0482
Luteolin	491-70-3	–	HPLC-UV (350 nm)	0.0098	0.0096–0.0103
Hydroxycinnamic acid derivatives					
Rosmarinic acid	20283-92-5	–	HPLC-UV (330 nm)	0.0653	0.0635–0.0662
Caffeic acid	331-39-5	–	HPLC-UV (320 nm)	0.0020	0.0020–0.0021
Ferulic acid	537-98-4	–	HPLC-UV (320 nm)	0.0005	0.0005–0.0006
p-Coumaric acid	501-98-4	–	HPLC-UV (310 nm)	0.0007	0.0006–0.0007
Volatile compounds					
Camphor[4]	76-22-2	–	GC-FID	0.0127	0.0124–0.0130
1,8-Cineole	470-82-6	03.001	GC-FID	0.0069	0.0067–0.0070
Thujones[5]	–	–	GC-FID	0.0129	0.0124–0.0132
Geraniol	106-24-1	02.012	GC-FID	0.0003	0.0002–0.0003
Linalool	78-70-6	02.013	GC-FID	0.0009	0.0009–0.0010
α-Terpineol	98-55-5	02.013	GC-FID	0.0004	0.0004–0.0004
4-Terpinenol	562-74-3	02.072	GC-FID	0.0009	0.0009–0.0010
Eugenol	97-53-0	04.003	GC-FID	0.0002	0.0001–0.0002
Carvacrol	499-75-2	04.031	GC-FID	0.0002	0.0002–0.0002
β-Caryophyllene	87-44-5	01.007	GC-FID	0.0001	0.0001–0.0002
α-Pinene	80-56-8	01.004	GC-FID	0.0010	0.0009–0.0010

Abbreviations: CAS no, Chemical Abstracts Service number; EU, European Union; FLAVIS no, EU Flavour Information System number; GC-FID, gas chromatography coupled with flame ionisation detection; HPLC, high-performance liquid chromatography; UV, ultraviolet.

[1]Expressed as gallic acid equivalents (GAE).

[2]Determined by an internal method based on European Pharmacopoeia (PhEur, 2022a). Chapter 2.8.14, Determination of tannins in herbal drugs.

[3]Determined by an internal method based on European Pharmacopoeia (PhEur, 2022b). Determination of flavonoids in motherwort.

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

[5]Present in the additive as a mixture of α-thujone (CAS no 546–80-5) and β-thujone (CAS no 471–15-8), the ratio between α- and β-thujones not given.

According to existing monographs (PhEur, 2022a; PhEur Commentary, 2020; EMA, 2016b) the dried leaves of *S. officinalis* are known to contain a fraction of up to 6.74% phenolic compounds (determined with Folin–Ciocalteu reagent) and up to 3% essential oil (main components: 1%–15% 1,8-cineole, 10%–60% α-thujone, 4%–36% β-thujone, 5%–35% camphor). The phenolic fraction consists of (i) hydroxycinnamic acid derivatives (about 3.5% of dried leaves): rosmarinic acid (main phenolic component), other derivatives of caffeic acid (sage, coumarin, salvianolic acids, sagerinic acid), free caffeic acid, (ii) phenolic diterpenes: e.g. carnosol, rosmanol, epirosmanol, 7-methoxy-rosmanol and (iii) flavonoids (0.4%–1.1% of dried leaves): e.g. luteolin, 6-hydroxyluteolin, 6-methoxyluteolin, apigenin, 6-methoxyapigenin and their glycosides.

The EFSA Compendium of botanicals[21] reports as substances of potential concern for human and animal health the occurrence of 1,8 cineole (2.7%–45.3%), α-thujone (3%–26.6%), β-thujone (1.13%–25.05%), camphor (11.3%–29.8%) and myrcene (0.1%–4.2%) in the essential oil from the aerial parts or the leaves of *S. officinalis*. The applicant made a literature search for the chemical composition of *S. officinalis* and its botanical preparations and the possible presence of substances of concern,[22] the results of which confirmed the information in the EFSA Compendium. In addition, the literature search identified a publication reporting the presence of pulegone (37.16%) in an essential oil from *S. officinalis* (Al-Mijalli et al., 2022). Among the publications retrieved by the literature search, a paper (Boufadi et al., 2021) reporting the qualitative and quantitative composition of the phenolic fraction of an aqueous alcoholic extract of *S. officinalis* leaves (80/20),

[18]Technical dossier/Supplementary information April 2024/ Annex II_8_Detailed report of Sage tincture HPTLC analysis.

[19]Technical dossier/Supplementary information April 2024/Annex_II_9_Certificate of analysis of rosmarinic acid in sage tincture.

[20]Technical dossier/Supplementary information April 2024/ Annex II_7_Certificate of analysis of camphor, thujones, 1,8-cineole and estragole in sage tincture.

[21]Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals, accessed on 15 May 2025.

[22]Technical dossier/Supplementary information April 2024/Annex II_5_Bibliographic data concerning composition of *Salvia officinalis* and its extracts.

was selected to retrieve more information on the composition of the additive. The phenolic components were identified by HPLC separation and UV detection at 270 and 320 nm by comparison with standard compounds. Rosmarinic acid and salvianolic acid, comprising 10% and 8% of the total phenolic fraction, respectively, were the most abundant phenolic compounds present in the extract. Other phenolic acids identified, comprising 22% of the phenolic fraction, were caffeic acid, sagerinic acid, carnosic acid, ferulic acid and gallic acid. Also 13 flavonoids were identified with a total content of 60% of the phenolic fraction. Among these were catechin, quercetin, rutin, kaempferol, luteolin, hesperidin, acacetin, cirsimaritin, pinocembrin, apigenin, apigenin-actetylglucoside, chrysin and hispidulin.

3.3.1.1 | *Impurities*

The applicant controls contamination at the level of the raw material, including knowledge of the cultivation conditions and pesticides applied. Specifications are set with suppliers covering cadmium, mercury, lead and arsenic, mycotoxins, pesticides, dioxins and polychlorinated biphenyls (PCBs) and microbial contamination.[23] An example of a quality control certificate of the raw material was provided. The applicant stated that analysis of impurities in the tincture is made on an irregular basis and does not form part of the Hazard Analysis and Critical Control Points (HACCP) plan. However, no data were provided on the presence of these impurities in the additive under assessment.

3.3.2 | Shelf life

The shelf life of the tincture is declared by the applicant to be at least 36 months when stored in tightly closed containers under standard conditions. No evidence was provided to support this claim.

3.3.3 | Conditions of use

The additive is intended for use in feed and in water for drinking for all animal species. The applicant proposes a maximum concentration of 500 mg sage tincture/kg complete feed for all animal species. No use level has been proposed for the use in water for drinking.

3.4 | Safety

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

Sage tincture contains plant-derived proteins, lipids and sugars (see Table 1), which are not of concern and are not further considered.

Among the secondary plant metabolites, total phenolic compounds were quantified, but only rosmarinic acid, caffeic acid, *p*-coumaric acid and ferulic acid were individually identified and quantified. Hydroxycinnamic acid derivatives (rosmarinic acid, caffeic acid, *p*-coumaric acid and ferulic acid) are ubiquitous in food and feeds of plant origin. They are readily metabolised and excreted and are not expected to accumulate in animal tissues and products. These compounds are not of concern at concentrations resulting from the use of the additive at the maximum proposed use level in feed and are not further considered in the assessment.

Several individual components identified in the tincture 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) superseded in 2008 by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). The flavouring compounds currently authorised for food[24] and/or feed[25] use, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000,[26] and the corresponding EFSA opinion are listed in Table 3.

[23]Technical dossier/Supplementary information April 2024/ Annex II_1_Sage leaves description form plant supplier and certificate of analysis of raw material.

[24]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.

[25]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.

[26]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 3 Flavouring compounds identified among the components of sage tincture, which were already assessed by EFSA 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 opinion.

CG	Chemical group	Product (EU register name)	FLAVIS no	EFSA* opinion, year
03	α,β-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters	Geraniol	02.012	2016a
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a
		α-Terpineol	02.014	
		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	Camphor	–	2008, AFC
		d-Camphor[1]	07.215	2016b, 2023
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012b, 2021
18	Allylhydroxybenzenes	Eugenol	04.003	2011
25	Phenol derivatives containing ring-alkyl, ring-alkoxy and side-chains with an oxygenated functional group	Carvacrol	04.031	2012c
31	Aliphatic and aromatic hydrocarbons	α-Pinene	01.004	2016c
		β-Caryophyllene	01.007	

[1]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, 2008) and in feed (EFSA FEEDAP Panel, 2016b).

*FEEDAP opinion unless otherwise indicated.

3.4.1 | Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals with the tincture under application were not submitted. In the absence of these data, the approach to the safety assessment of the mixture is based on the safety assessment of its individual components (when individually identified and quantified) or groups of components.

Camphor is assessed based on the results of the tolerance studies in the target species with the mixture of flavourings 'Herbal' (EFSA FEEDAP Panel, 2023).

For geraniol [02.012], linalool [02.013], terpineol [02.230], 1,8-cineole [03.001], eugenol [04.003], carvacrol [04.031] and β-caryophyllene [01.007], subchronic oral toxicity studies are available, from which no observed adverse effect levels (NOAELs) were identified (EFSA FEEDAP Panel, 2011, 2012a, 2012c, 2016a, 2016c, 2021). For thujones,[27] the FEEDAP Panel applied a benchmark dose lower confidence limit for a benchmark response of 10% ($BMDL_{10}$) derived from the long-term chronic toxicity study in mice and rats using clonic seizures as the critical effect (EFSA FEEDAP Panel, 2022).

For the group assessment of phenolic compounds including flavonoids, in the absence of data, the threshold of toxicological concern (TTC) is applied to derive maximum safe concentrations in feed for the whole groups in the tincture (EFSA FEEDAP Panel, 2017b).

3.4.1.1 | *Camphor*

Camphor (as a mixture of isomers) has not been evaluated for use as a flavouring. However, *d*-camphor 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 *d*-camphor was safe for the target species at 5 mg/kg complete feed (EFSA FEEDAP Panel, 2023). The FEEDAP Panel considers that the conclusions reached for *d*-camphor can be extrapolated to the mixture of isomers of camphor by applying read-across.

At the maximum proposed use level of 500 mg sage tincture/kg complete feed and considering the highest analysed concentration of camphor[28] (0.013%) in the tincture, the corresponding level of camphor in complete feed would be up to 0.065 mg/kg. This concentration is well below the safe concentration of *d*-camphor of 5 mg/kg complete feed considered safe for all animal species when tested in the mixture 'Herbal' (EFSA FEEDAP Panel, 2023). Therefore, no concern for the target species is expected from the presence of camphor in sage tincture.

[27]Present in the additive as a mixture of α- thujone and β-thujone, the ratio between α- and β-thujones not given.

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

3.4.1.2 | *Volatile compounds other than camphor*

The volatile compounds present in the tincture were allocated to six assessment groups, corresponding to the chemical groups (CGs) 3, 6, 16, 18, 25 and 31, as defined in Annex I of Regulation (EC) No 1565/2000. The allocation of the components to the assessment groups is shown in Table 4.

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[29]). For some components in the assessment group, toxicological data were available to identify NOAELs. Structural and metabolic similarity among the components in the assessment groups were 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 same group with no available NOAEL or, if sufficient evidence were available for members of an assessment group, to derive a group NOAEL.

Sub-chronic studies, from which NOAEL values (or a $BMDL_{10}$ value for thujones) could be identified, were available for the following volatile components of the tincture: 345 mg/kg body weight (bw) per day for geraniol [02.012] (EFSA FEEDAP Panel, 2016a), 117 mg/kg bw per day for linalool [02.013], 250 mg/kg bw per day for terpineol [02.230][30] (EFSA FEEDAP Panel, 2012a), 100 mg/kg bw per day for 1,8-cineole [03.001] (EFSA FEEDAP Panel, 2021), 300 mg/kg bw per day for eugenol [04.003], 36 mg/kg bw per day for carvacrol [04.031] (EFSA FEEDAP Panel, 2012c), 222 mg/kg bw per day for β-caryophyllene [01.007] (EFSA FEEDAP Panel, 2016c) and 11 mg/kg bw per day for thujones (EFSA FEEDAP Panel, 2022).

In CG 6, a NOAEL of 250 mg/kg bw per day was identified for terpineol [02.230], 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, α-terpineol [02.014] and 4-terpinenol [02.072]. In CG 31, the NOAEL of 222 mg/kg bw per day is applied to α-pinene [01.004].

For each component in the assessment group, exposure in target animals (expressed as mg/kg bw per day) was estimated considering the maximum proposed use level of 500 mg sage tincture/kg complete feed, the percentage of the component in the tincture, 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 each component, the highest analysed concentration in the additive is used.

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 for the individual substances (EFSA Scientific Committee, 2019a). A MOE(T) > 100 allowed for interspecies differences and intra-individual variability.

The approach to the safety assessment of sage tincture is shown in Table 4 for chickens for fattening, the species with the highest ratio of feed intake/body weight and which represents the worst-case scenario among the target species.

TABLE 4 Compositional data, intake values (calculated for chickens for fattening at 500 mg/kg complete feed), reference points and margin of exposure (MOE) for the individual components of sage tincture classified according to assessment groups, and combined margin of exposure (MOET) for each assessment group.

Tincture composition			**Exposure**		**Hazard characterisation**		**Risk characterisation**	
Assessment group	FLAVIS-no	Highest concentration in the tincture	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 4								
Geraniol	02.012	0.0003	0.0015	0.00013	(I)	345	2,562,025	
CG 6								
Linalool	02.013	0.0010	0.0050	0.00045	(I)	**117**	260,658	
α-Terpineol	02.014	0.0004	0.0020	0.00018	(I)	125[6]	696,203	
4-Terpinenol	02.072	0.0010	0.0050	0.00045	(I)	125[6]	278,481	
MOET CG 6								**112,820**
CG 16								
1,8-Cineole	03.001	0.0069	0.0345	0.00310	(II)	**100**	32,288	
CG 18								
Eugenol	04.003	0.0002	0.0010	0.00009	(I)	**300**	3,341,772	

(Continues)

[29]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/.

[30]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.

TABLE 4 (Continued)

Tincture composition			Exposure		Hazard characterisation		Risk characterisation
CG 25							
Thymol	04.006	0.0002	0.0010	0.00009	(I)	36	401,013
CG 31							
β-Caryophyllene	01.007	0.0001	0.0005	0.00004	(I)	**222**	4,945,823
α-Pinene	01.004	0.0010	0.0050	0.00045	(I)	222	494,582
Group MOE CG 31							**449,620**
Thujones	–	0.0129	0.0645	0.00579	(III)	**11**	1900

Abbreviations: bw, body weight; FLAVIS, EU Flavour Information System; 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.

As shown in Table 4, for all assessment groups the MOE(T) calculated for chickens for fattening at the maximum proposed use level of 500 mg sage tincture/kg complete feed was substantially > 100. Therefore, no safety concern was identified for the volatile components of sage tincture when used as a feed additive for chickens for fattening at the maximum proposed use level (500 mg/kg complete feed). As chickens for fattening is the species with the highest ratio of feed intake/body weight and represent the worst-case scenario, the same conclusion can be extended to all animal species.

3.4.1.3 | *Flavonoids*

At the maximum proposed use level of 500 mg sage tincture/kg complete feed, the highest concentration of flavonoids (0.048% of the tincture) would be up to 0.241 mg/kg complete feed. Since the individual compounds were not identified, they are assigned to Cramer Class III. A comparison between the highest concentration of flavonoids in feed resulting from the use of the additive at the maximum proposed use level of 500 mg/kg and the maximum acceptable concentrations in feed for Cramer Class III compounds (EFSA FEEDAP Panel, 2017b) is shown in Table 5.

TABLE 5 Highest concentration of flavonoids from sage tincture in complete feed, calculated at the maximum proposed use level of 500 mg/kg complete feed and maximum safe concentrations of flavonoids and of the additive in feed for the target species calculated by applying the threshold of toxicological concern for Cramer Class III compounds.

Animal category	Daily feed intake (g DM/kg bw)	Highest concentration of flavonoids[1] (mg/kg complete feed)[2]	Maximum safe concentration of flavonoids (mg/kg complete feed)[2]	Maximum safe concentration of sage tincture (mg/kg complete feed)[2]
Chickens for fattening	79	0.241	0.02	35
Laying hens	53	0.241	0.02	52
Turkeys for fattening	59	0.241	0.02	47
Piglets	44	0.241	0.03	62
Pigs for fattening	37	0.241	0.04	75
Sows lactating	30	0.241	0.04	91
Veal calves (milk replacer)	19	0.241	0.08	145
Cattle for fattening	20	0.241	0.07	137
Dairy cows	31	0.241	0.04	89
Sheep/goats	20	0.241	0.07	137
Horses	20	0.241	0.07	137
Rabbits	50	0.241	0.03	55
Salmonids	18	0.241	0.08	156
Dogs	17	0.241	0.08	164

TABLE 5 (Continued)

Animal category	Daily feed intake (g DM/kg bw)	Highest concentration of flavonoids[1] (mg/kg complete feed)[2]	Maximum safe concentration of flavonoids (mg/kg complete feed)[2]	Maximum safe concentration of sage tincture (mg/kg complete feed)[2]
Cats	20	0.241	0.07	137
Ornamental fish	5	0.241	0.29	–[3]

Abbreviations: bw, body weight; DM, dry matter.

[1]Calculated at the proposed use level of sage tincture in complete feed (500 mg/kg) and considering the highest analysed concentration of flavonoids in the additive (0.048%, w/w).

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

[3]The proposed use level of 500 mg/kg complete feed is considered safe.

The results shown in Table 5 indicate that the concentration of flavonoids in feed would be above the maximum acceptable concentration for Cramer Class III compounds in feed for all animal categories except ornamental fish. For ornamental fish, the maximum proposed use level of 500 mg/kg complete feed is safe when considering the presence of flavonoids. For the other animal categories, the calculated maximum safe concentrations of sage tincture in feed for the target species (when considering only the flavonoid fraction) are shown in Table 5.

3.4.1.4 | *Polyphenols other than flavonoids, rosmarinic acid, caffeic acid,* p*-coumaric acid and ferulic acid*

Among the secondary metabolites, up to 0.328% of the tincture are polyphenols measured by the Folin–Ciocalteu method and expressed as GAE. After subtraction of flavonoids, rosmarinic acid, caffeic acid, *p*-coumaric acid and ferulic acid, the fraction of polyphenols is 0.217% of the tincture. At the maximum proposed use level of 500 mg sage tincture/kg complete feed, this would equate to 1.09 mg/kg complete feed. Although the individual components of this fraction were not identified, the results of the literature search provided by the applicant (see Section 3.3.1) indicated that substances belonging to Cramer class III are not expected in the polyphenolic fraction. Unidentified flavonoids have been separately assessed by applying the TTC for Cramer Class III compounds (see Section 3.4.1.3). Therefore, the remaining polyphenols belonging to this fraction are assigned to Cramer Class I and assessed as a group. A comparison between the highest concentration of polyphenols in feed resulting from the use of the additive at the maximum proposed use level of 500 mg/kg in complete feed and the maximum acceptable concentrations in feed for Cramer Class I compounds (EFSA FEEDAP Panel, 2017b) is shown in Table 6.

TABLE 6 Highest concentration of polyphenols (after subtraction of flavonoids, rosmarinic acid, caffeic acid, *p*-coumaric acid and ferulic acid from the value determined by Folin–Ciocalteu method) from sage tincture in complete feed, calculated at the maximum proposed use level of 500 mg/kg complete feed, and maximum safe concentrations in feed of polyphenols and of the additive for the target species calculated by applying the threshold of toxicological concern for Cramer Class I compounds.

Animal category	Daily feed intake (g DM/kg bw)	Highest concentration of polyphenols[1] (mg/kg complete feed)[2]	Maximum safe concentration of polyphenols (mg/kg complete feed)[1]	Maximum safe concentration of sage tincture (mg/kg complete feed)[1]
Chickens for fattening	79	1.09	0.3	154
Laying hens	53	1.09	0.5	229
Turkeys for fattening	59	1.09	0.5	207
Piglets	44	1.09	0.6	276
Pigs for fattening	37	1.09	0.7	331
Sows lactating	30	1.09	0.9	402
Veal calves (milk replacer)	19	1.09	1.5	–[3]
Cattle for fattening	20	1.09	1.3	–
Dairy cows	31	1.09	0.9	395
Sheep/goats	20	1.09	1.3	–
Horses	20	1.09	1.3	–
Rabbits	50	1.09	0.5	243
Salmonids	18	1.09	1.5	–
Dogs	17	1.09	1.6	–
Cats	20	1.09	1.3	–
Ornamental fish	5	1.09	5.9	–

Abbreviations: bw: body weight; DM: dry matter.

[1]Calculated at the proposed use level of sage tincture in complete feed (500 mg/kg) and considering the highest estimated analysed value of polyphenols (after subtraction of flavonoids, rosmarinic acid, caffeic acid, *p*-coumaric acid and ferulic acid) in the additive (0.217%, w/w).

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

[3]The proposed use level of 500 mg/kg complete feed is considered safe.

The results shown in Table 6 indicate that the concentration of polyphenols in feed (after subtraction of flavonoids, rosmarinic acid, caffeic acid, *p*-coumaric acid and ferulic acid) would be above the maximum acceptable concentration for Cramer Class I compounds in feed for poultry, pigs, dairy cows and rabbits. For these species, the calculated safe concentrations of sage tincture (when considering only polyphenols) in feed for the target species are shown in Table 6. For veal calves, cattle for fattening, sheep/goats, horses, salmonids, dogs, cats and ornamental fish the maximum proposed use level of 500 mg/kg complete feed is safe (when considering only polyphenols).

Overall evaluation

When considering the assessment of the individual components or groups of components of sage tincture, the lowest safe concentrations in feed were derived for the assessment group flavonoids (see Table 5). These levels are extrapolated to physiologically related species. For the other species not considered, the calculated maximum safe level of 35 mg additive/kg complete feed is applied.

No specific proposals have been made by the applicant for the use 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.

3.4.1.5 | *Conclusions on safety for the target species*

The FEEDAP Panel considers that the use of sage tincture is safe for the target species up to the maximum concentrations in complete feed summarised in Table 7.

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

Animal categories	Safe concentration (mg/kg complete feed)[1]
Turkeys for fattening	47
Chickens for fattening, other poultry for fattening or reared for laying/reproduction and ornamental birds	35
Laying hens and other laying/reproductive birds	52
Piglets and other porcine species for meat production or reared for reproduction	62
Pigs for fattening	75
Sows and other porcine species for reproduction	91
Veal calves (milk replacer)	156
Sheep/goats	137
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction and camelids at the same physiological stage	137
Dairy cows and other ruminants and camelids for milk production or reproduction	89
Horses and other equids	137
Rabbits and other leporids	55
Salmonids and minor fin fish	156
Dogs	164
Cats	137
Ornamental fish	500
Other species	35

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

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.

3.4.2 | Safety for the consumer

The leaves of *S. officinalis* L. (sage) and their oil are 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 intake values of 2.25 mg/kg bw per day for sage (FEMA 3000) and 0.016 mg/kg bw per day for sage oil (FEMA 3001). Fenaroli also reports use levels of sage oil in food and beverages in the range of 3 mg/kg up to 225 mg/kg.

No data on residues in products of animal origin were made available for any of the constituents of the tincture. When considering the absorption, distribution, metabolism and excretion (ADME) of the individual components, the data

available for 1,8-cineole, camphor and thujones indicate that they are absorbed, metabolised and rapidly excreted and are not expected to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2012b, 2016b, 2021). Similarly, the phenolic compounds including flavonoids, will be readily metabolised and excreted and are not expected to accumulate in animal tissues and products. Consequently, relevant residues in food products of animal origin are unlikely.

Considering the above and the reported human exposure due to the direct use of sage and its preparations in food (Burdock, 2009), it is unlikely that consumption of products from animals given sage tincture in the diet at the maximum proposed use level would significantly increase human background exposure.

No safety concern would be expected for the consumer from the use of sage tincture up to the maximum proposed use level in feed.

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 information according to Classification, Labelling and Packaging (CLP) Regulation (EC) 1272/2008[31] concerning the presence of ethanol in the tincture.[32]

The additive contains camphor and 1,8-cineole, compounds for which hazards for skin and eye contact and respiratory exposure were recognised (EFSA FEEDAP Panel, 2012a, 2016b).

The additive under assessment should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. Any exposure is considered a risk.

3.4.4 | Safety for the environment

S. officinalis is a species native to and widely distributed in Europe, where it grows wild and it is also cultivated for culinary and ornamental purposes.

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

3.5 | Efficacy

The leaves of sage (*S. officinalis* L.) and their oil are listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by FEMA with the reference numbers 3000 and 3001, respectively.

Since the leaves of *S. officinalis* and their preparations are recognised to flavour food and their 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 of sage tincture in complete feed for all animal species are summarised as follows:

Animal categories	Safe concentration (mg/kg complete feed)[1]
Turkeys for fattening	47
Chickens for fattening, other poultry for fattening or reared for laying/reproduction and ornamental birds	35
Laying hens and other laying/reproductive birds	52
Piglets and other porcine species for meat production or reared for reproduction	62
Pigs for fattening	75
Sows and other porcine species for reproduction	91
Veal calves (milk replacer)	156
Sheep/goats	137

(Continues)

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

[32]H319: causes serious eye irritation (relevant for dermal exposure).

(Continued)

Animal categories	Safe concentration (mg/kg complete feed)[1]
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction and camelids at the same physiological stage	137
Dairy cows and other ruminants and camelids for milk production or reproduction	89
Horses and other equids	137
Rabbits and other leporids	55
Salmonids and minor fin fish	156
Dogs	164
Cats	137
Ornamental fish	500
Other species	35

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

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.

The use of sage tincture at the proposed conditions of use is considered safe for the consumers and the environment.

Regarding user safety, the additive under assessment should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. Any exposure is considered a risk.

Since the leaves of *S. officinalis* and their preparations are recognised to flavour food and their 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
27/02/2019	Partial withdrawal of application for the following additives: thyme leaves gratiola tincture, spike lavender oil, melissa oil, pennyroyal oil, basil oil and savory 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 marjoram oil
04/04/2024	Reception of supplementary information from the applicant (partial dataset: sage tincture) – Scientific assessment remains suspended
08/07/2024	Partial withdrawal of the application for the following additives: lilac chastetree extract and savory summer tincture
17/07/2024	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*
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)
14/01/2025	Reception of supplementary information from the applicant (partial dataset: basil tincture, lavender tincture, peppermint tincture, sage tincture and wild thyme tincture) – Scientific assessment remains suspended

(Continued)

Date	Event
26/05/2025	The application was split and a new EFSA-Q-2025-00328 was assigned to the additive included in the present assessment
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
23/06/2025	Scientific assessment re-started for the additive included in the present assessment
24/06/2025	Opinion adopted by the FEEDAP Panel on sage tincture (EFSA-Q-2025-00328). 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

ADME	absorption, distribution, metabolism and excretion
AFC	EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
BDG	botanically defined group
BMD	Benchmark dose
$BMDL_{10}$	benchmark dose (BMD) lower confidence limit for a benchmark response of 10%
BW	body weight
CAS	Chemical Abstracts Service
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CLP	Classification, Labelling and Packaging
CoE	Council of Europe
DM	dry matter
EEIG	European economic interest grouping
EMA	European Medicines Agency
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FEMA	Flavour and Extract Manufactures Association
FFAC	Feed Flavourings authorisation Consortium of FEFANA (EU Association of Specialty Feed Ingredients and their Mixtures)
FLAVIS	The EU Flavour Information System
GAE	gallic acid equivalent
GC-FID	gas chromatography-flame ionisation detection
HACCP	Hazard Analysis and Critical Control Points
HPLC	high-performance liquid chromatography
HPTLC	high-performance thin layer chromatography
JECFA	Joint FAO/WHO Expert Committee of Food Additives
LOD	limit of detection
MOE	margin of exposure
MOE(T)	(total) margin of exposure
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyl
PhEur	European Pharmacopoiea
SC	EFSA Scientific Committee
TTC	threshold of toxicological concern
UV	ultraviolet
WHO	World Health Organization

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REQUESTOR

European Commission

QUESTION NUMBER

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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 and Katerina Theodoridou.

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