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Safety and efficacy of feed additives consisting of rosemary tinctures obtained from the leaves of *Salvia rosmarinus* Spenn. for use in all animal species (FEFANA asbl)

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., Benfenati, E., Brantom, P., ... EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) (2025). Safety and efficacy of feed additives consisting of rosemary tinctures obtained from the leaves of *Salvia rosmarinus* Spenn. for use in all animal species (FEFANA asbl). *EFSA Journal*, 23(10), Article e9686. <https://doi.org/10.2903/j.efsa.2025.9686>

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Safety and efficacy of feed additives consisting of rosemary tinctures obtained from the leaves of *Salvia rosmarinus* Spenn. 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 two tinctures obtained from the leaves of *Salvia rosmarinus* Spenn. (rosemary tinctures) when used as sensory additives. The tinctures are water/ethanol solutions, with a dry matter content of 4.43% (tincture A) and 1.28% (tincture B). Tincture A is proposed for use in feed for chickens for fattening, laying hens, horses and dogs, while tincture B is intended for use in feed and water for drinking for all animal species. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the additives under assessment are safe for the target species at the maximum proposed use level of 500 mg/kg complete feed: (i) rosemary tincture A for chickens for fattening, laying hens, horses and dogs; (ii) rosemary tincture B for all animal species. The FEEDAP Panel considered that, for tincture B, 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. No safety concern would arise for the consumer and the environment from the use of rosemary tinctures in animal feed. Regarding user safety, the additives under assessment should be considered as irritants to skin and eyes, and as dermal and respiratory sensitisers. Any exposure is considered a risk. Since the leaves of *S. rosmarinus* 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 considered necessary.

KEYWORDS

1,8-cinole, camphor, flavouring compounds, rosemary tincture, rosmarinic acid, *Salvia rosmarinus* Spenn., sensory additives

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003¹ 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, devil's claw extract, devil's 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 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 of the remaining 29 additives under application: rosemary tinctures for use in all animal species.

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

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive). 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 rosemary tinctures when used under the proposed conditions of use (see **Sections 3.3.1.3 and 3.3.2.3**).

1.2 | Additional information

Rosemary tincture from *Rosmarinus 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. It should be noted that the designation *Rosmarinus officinalis* L. is no longer accepted by the botanical community and the species has been moved to the genus *Salvia* with the species name *Salvia rosmarinus* Spenn. However, *Rosmarinus officinalis* L. is used in the opinion when citing literature (e.g. PhEur, EMA monographs) and the EFSA Compendium on botanicals.

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of rosemary tinctures from *S. rosmarinus* as feed additives. The dossier was received on 26 June 2025, and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2025-00404>.⁶

¹Regulation (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.

²On 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.

³Thyme leaves gratiola tincture, spike lavender oil, melissa oil, pennyroyal oil, basil oil and savoury summer oil (27 February 2019); Spanish marjoram oil (28 September 2023); lilac chastetree extract and savoury summer tincture (8 July 2024); devil's claw extract (wb), balm leaves extract (sb), olive extract (sb) (16 December 2024).

⁴Register of feed additives, Annex II, withdrawn by OJ L162, 10.05.2021, p. 5.

⁵Dossier reference: FAD-2010-0137.

⁶The original application EFSA-Q-2010-0137 was split on 26/06/2025 and a new EFSA-Q-2025-00404 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 already been evaluated by the FEEDAP Panel as chemically defined flavourings (CDGs). The applicant submitted a written agreement to reuse the data submitted for the assessment of chemically defined flavourings (dossiers, publications and unpublished reports) for the risk assessment of preparations belonging to BDG 01, including the current ones under assessment.⁷

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the phytochemical markers in the additives. During the assessment, upon request of EFSA, the EURL issued two partial reports.⁸ The additive under assessment is included in the second partial report. In particular, for the characterisation of rosemary tinctures, the EURL recommended methods based on (i) spectrophotometry for the determination of total polyphenols; (ii) gas chromatography coupled with flame ionisation detection (GC-FID) for the determination of 1,8-cineole and camphor; (iii) high-performance liquid chromatography (HPLC) for the quantification of the phytochemical marker rosmarinic acid in rosemary tinctures.⁹

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and efficacy of rosemary tinctures from *S. rosmarinus* is in line with the principles laid down in Regulation (EC) No 429/2008¹⁰ 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,¹¹ Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019a), 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, 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

This application covers two tinctures, A and B, derived from the dried leaves of *Salvia rosmarinus* Spenn., referred to as rosemary tinctures. They are intended for use as sensory additives (functional group: flavouring compounds). Tincture A is proposed for use in feed for chickens for fattening, laying hens, horses and dogs, while tincture B is intended for use in feed and water for drinking for all animal species.

3.1 | Origin and extraction

Salvia rosmarinus Spenn. (homotypic syn. *Rosmarinus officinalis* L.), commonly referred to as rosemary, is an evergreen shrub belonging to the Lamiaceae family. It is native to the Mediterranean region and introduced into more northern parts of Europe and to southern parts of North America because of its ornamental value and the use of its leaves as a culinary herb. Rosemary may be found in many forms either growing with an upright habit (1–2 m in height) or as a trailing or creeping plant. It is characterised by its needle-like leaves, green on the upper and white on the lower surface. Flowers in season are randomly distributed along the stem and may be white, purple or blue in colour.

Following an extensive phylogenetic study of the genus *Salvia* and related genera (Drew et al., 2017), the taxonomic standing of the genus *Rosmarinus* has been revised and the species described for this genus moved to the genus *Salvia*. As a

⁷Technical dossier/Supplementary information August 2024/Letter dated 27/08/2024.

⁸Additives 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.

⁹Evaluation 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.

¹⁰Commission 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.

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

consequence, *Rosmarinus* is no longer considered an accepted genus, although the synonym for *S. rosmarinus* (*Rosmarinus officinalis*) may still be found associated with descriptions involving the rosemary plant and its extracts.

Tincture A is obtained by extraction of the dried leaves of rosemary (originating from Morocco) using a water/ethanol mixture (40:60, v/v). The ratio of dry raw material to solvent is 1:5 (w:v). Following maceration for 3 weeks, the tincture is obtained by pressing to remove solid material and then clarified by filtration.

Tincture B is also produced from the dried leaves of rosemary (originating from the Mediterranean area) by extended extraction for [REDACTED] under ambient conditions with a [REDACTED] solvent mixture and a [REDACTED]. The tincture is obtained by pressing to remove solid material and then clarified by filtration.

3.2 | Uses other than feed flavourings

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

‘Rosemary leaf (*Rosmarini folium*)’ from *R. officinalis* L. is described in monographs of the European Pharmacopoeia 11.0 (PhEur, 2022a) and of the European Medicines Agency (EMA, 2024a, 2024b) for medicinal uses.

3.3 | Characterisation

There is no Chemical Abstract Service (CAS) number or European Community (EC) number listed which applies specifically to a rosemary tincture.¹³ The Council of Europe (CoE) number 406 covers any extract of *Rosmarinus officinalis* L.

3.3.1 | Characterisation of tincture A

Tincture A has a density of 918–993 kg/m³ (956 kg/m³ on average). The additive is a water/ethanol (40/60, v/v) solution, which contains by specification not more than 6% of plant-derived compounds, including 0.01%–0.1% 1,8-cineole (selected as the phytochemical marker) and 0.005%–0.05% camphor.¹⁴

Table 1 summarises the results of the proximate analysis of five batches of the tincture A expressed as % of the tincture (w/w).¹⁵ The solvent represents on average 95.6% of the additive, leaving a dry matter (DM) content of 4.4% (w/w). The DM consists of inorganic material measured as ash (7.15%), sugars (16.5%), lipids (15.2%) and proteins (5.34%). 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 (Table 2).

TABLE 1 Proximate analysis of a rosemary tincture A, based on the analysis of five batches.

Constituent	Mean	Range
	% (w/w)	% (w/w)
Dry matter	4.43	4.25–4.56
Ash	0.32	0.3–0.4
Sugars	0.74	0.6–0.8
Lipids	0.68	0.6–0.7
Protein	0.24	0.2–0.3
Fibre	<0.2	<0.2
Starch	<0.5	<0.5
‘Unidentified’ ¹	1.75	1.66–1.84
Solvent (water/ethanol, 40/60, v/v)	95.6	95.4–95.8

¹‘Unidentified’ (by difference) calculated subtracting ash, proteins, lipids and sugar from the dry matter. It includes non-volatile secondary plant metabolites.

¹²Regulation (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.

¹³The following entries were found at <https://echa.europa.eu> home: ‘Rosemary, ext. (Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Rosmarinus officinalis*, Labiatae)’, CAS 84604-14-8; EC number 283-291-9.

¹⁴Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/SIn_reply_rosemary_tincture.

¹⁵Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex I_Rosemary tincture_Proximate analysis and impurities.

The fraction of secondary metabolites was characterised in the same batches of the additive and the results are summarised in Table 2. Total phenolic compounds determined by spectrophotometry (at 760 nm) are expressed as gallic acid equivalents (GAE).¹⁶ Individual compounds were determined by high performance liquid chromatography (HPLC) with ultraviolet (UV) detection: phenolic compounds (at 320 nm) including flavonoids, caffeoylquinic acids (neochlorogenic acid) and other hydroxycinnamic acid derivatives (350 nm),¹⁷ phenolic diterpenes (carnosic acid derivatives, 220 nm),¹⁸ triterpenes and shogaols (209 nm),¹⁹ and other organic acids (detected at 210 nm).²⁰ The tincture also contained volatile compounds²¹ identified and quantified by gas chromatography–mass spectrometry (GC–MS).

TABLE 2 Characterisation of the fraction of secondary metabolites of rosemary tincture A, based on the analysis of five batches (mean and range).

Constituent	CAS No	Mean µg/mL	Range µg/mL
Phenols¹ (total, by photometry)	–	5315	4560–5617
Flavonoids (HPLC, 320 nm)			
Luteolin 3'-O-glucuronide	53527-42-7	1295	1222–1415
Luteolin-3'-O-β-D-glucuronic- acid-6''-methyl ester	491-70-3	314.6	280.6–396.8
Luteolin-3'-acetylglucuronide (Isomer I or II)	491-70-3	339.3	266.7–542.8
Nepitrin	569-90-4	194.7	185.9–212.3
Luteolin-3'-acetylglucuronide (Isomer I or II)	491-70-3	156.1	119.9–255.4
Luteolin-7-glucuronide	29741-10-4	153.3	143.1–164.0
Luteolin derivative	491-70-3	86.8	79.5–94.5
Genkwanin	437-64-9	73.9	58.0–84.7
Homoplantagin	17680-84-1	72.0	64.2–85.3
Cirsimaritin	6601-62-3	60.4	55.7–63.5
Flavone 5 (genkwanin derivative)	437-64-9	28.0	18.5–37.9
Flavone 1 (apigenin derivative)	520-36-5	22.6	14.1–38.0
Flavone 3	520-36-5	18.5	17.1–19.8
Acacetin	480-44-4	17.5	12.8–25.2
Flavone 4 (quercetin derivative)	117-39-5	16.6	15.9–18.3
Apigenin	520-36-5	15.3	11.7–20.7
6''-O-(E)-Feruoyl-homoplantagin	–	14.4	13.9–14.8
Flavone 2 (apigenin derivative)	520-36-5	11.2	10.5–12.4
Total flavonoids		2890 ²	2711–3426 ³
Hydroxycinnamic acid derivatives (HPLC, 320 nm)			
Rosmarinic acid	20283-92-5	2281	1997–2483
Cinnamic acid derivative 1	–	81.3	74.7–86.7
Cinnamic acid derivative 2	–	54.5	42.4–63.1
Cinnamic acid derivative 3	–	80.1	66.8–90.2
Cinnamic acid derivative 4	–	60.3	52.9–63.5
Caffeic acid	331-39-5	47.5	40.7–59.3
Neochlorogenic acid	906-33-2	34.5	26.3–46.8
Total hydroxycinnamic acid derivatives		2639 ²	2338–2792 ³

¹⁶Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex_II_Rosemary_tincture_Total_Phenols (Tannins).
¹⁷Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex_IV_Rosemary_tincture_Caffeoylquinic Acids & Flav.
¹⁸Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex_V_Rosemary_tincture_Carnosic Acid derivatives.
¹⁹Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex_VI_Rosemary_tincture_Triterpenic Acid derivatives.
²⁰Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex_III_Rosemary_tincture_Organic acids_Rosemary_tincture.
²¹Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex_VII_Essential oil compounds.

TABLE 2 (Continued)

Constituent	CAS No	Mean µg/mL	Range µg/mL
Phenolic diterpenes and derivatives (HPLC, 220 nm)			
Methyl Carnosate	82684-06-8	331.4	300.5–368.2
Epirosmanol-Ethylether	–	159.7	55.6–213.1
Rosmanol-Ethylether	–	66.7	40.5–78.8
Carnosol	5957-80-2	37.7	10.6–99.7
Rosmanol	80225-53-2	11.4	4.60–25.49
Carnosol (decomposition product)	–	16.0	0.00–31.20
12-Methyl-carnosol	–	9.63	9.02–10.69
5,6,7,10-tetra-hydro-7-OH-Rosmariquinone ^d	–	4.06	0.00–8.03
Epirosmanol	93380-12-2	3.73	1.95–5.68
Epiisorosmanol	87980-67-4	1.03	0.00–1.80
Total phenolic diterpene derivatives		641.3 ²	463.2–713.4 ³
Shogaols (HPLC, 209 nm)			
Shogaol-like compound 1	–	63.1	40.9–82.8
Shogaol-like compound 2	–	23.0	21.2–25.9
Total shogaols		86.1 ²	66.8–106.0 ³
Triterpenes (HPLC, 209 nm)			
Betulinic acid	472-15-1	105.8	84.6–129.8
Micromeric acid	22477-85-6	70.1	52.4–105.4
Oleanolic Acid	508-02-1	52.1	42.0–58.3
Ursolic Acid	77-52-1	49.0	35.1–59.4
Total triterpenes		277.0 ²	242.4–298.3 ³
Other organic acids (HPLC, 220 nm)			
Quinic acid	36413-60-20	2075	1444–2635
Shikimic acid	138-59-0	24.5	17.4–35.0
3,4-Dihydroxybenzoic acid	99-50-3	9.91	9.25–11.22
Total other organic acids		2110	1473–2676
Total identified ⁵		8643 ²	7728–9700 ³

Constituent	CAS no	FLAVIS no	Mean, µg/mL	Range, µg/mL
Volatile compounds (GC–MS)				
Oct-1-en-3-ol	3391-86-4	02.023	1.98	0.85–2.49
Linalool	78-70-6	02.013	18.4	15.3–20.9
4-Terpinenol	562-74-3	02.072	15.94	13.3–17.84
α-Terpineol	98-55-5	02.014	80.6	73.8–86.3
1,3-p-Menthadien-7-al	1197-15-5	05.133	1.38	1.26–1.46
cis-Sabinene hydrate	15537-55-0	–	0.51	0.23–0.94
Fenchyl alcohol	1632-73-1	02.038	1.01	0.73–1.23
Camphor ⁶	76-22-2	–	277.2	205.42–328.2
d,l-Borneol	507-70-0	02.016	78.2	69.6–90.1
Verbenone (pin-2-en-4-one)	80-57-9	07.196	4.92	1.35–8.27
1,8-Cineole	470-82-6	03.001	618.8	587.2–647.4
4-Iopropylbenzyl alcohol	536-60-7	02.039	1.44	1.38–1.53
Thymol	89-83-8	04.006	50.0	50.0
Carvacrol	499-75-2	04.031	1.85	1.59–2.21
Methyl 3-oxo-2-pent-2-enyl-1-cyclopentylacetate	39924-52-2	09.521	15.8	14.0–18.6
Myrcene	123-35-3	01.008	2.18	1.75–2.54
α-Phellandrene	99-83-2	01.006	0.37	0.27–0.45

(Continues)

TABLE 2 (Continued)

Constituent	CAS no	FLAVIS no	Mean, µg/mL	Range, µg/mL
α-Terpinene	99-86-5	01.019	1.30	1.01–1.63
γ-Terpinene	99-85-4	01.020	1.22	1.04–1.44
p-Cymene (1-isopropyl-4-methylbenzene)	99-87-6	01.002	9.19	7.77–10.6
14-Hydroxycaryophyllene	–		15.8	13.7–17.8
β-Caryophyllene	87-44-5	01.007	15.7	13.3–18.3
α-Pinene (pin-2(3)-ene)	80-56-8	01.004	54.3	46.7–60.3
Camphene	79-92-5	01.009	14.3	12.4–16.2
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	5.54	4.69–6.34
3,7,10-Humulatriene	6753-98-6	01.043	2.26	1.88–2.60
β-Caryophyllene epoxide	1139-30-6	16.043	12.2	10.5–13.6
Humulene oxide II	19888-34-7	02.023	1.77	1.50–2.13
Total volatiles			1304 ²	1189–1399 ³

Abbreviations: CAS No, Chemical Abstracts Service number; FLAVIS No, EU Flavour Information System numbers; HPLC, high performance liquid chromatography.

¹Expressed as gallic acid equivalents (GAE).

²The value given for the Total (mean) is the mean of the sum of the constituents in the individual batches.

³The values given for the total (range) are the lowest and the highest values of the sum of the constituents in the batches analysed.

⁴5,6,7,10-tetra-hydro-7-OH-Rosmariquinone is not a phenolic compound; therefore, it is not included in the sum of total phenolic diterpene derivatives.

⁵Calculated as the sum of flavonoids, hydroxycinnamic acid derivatives, phenolic diterpenes and derivatives, shogaols, triterpenes, and organic acids.

⁶Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers is not given. JECFA and EFSA evaluated the enantiomer *d*-camphor (name in the register: (1*R*)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one [07.215]) for use in food (EFSA, 2008) and in feed (EFSA FEEDAP Panel, 2016a, 2016b).

Tincture A was shown to contain as % w/w²² triterpenic acids up to 0.032% (corresponding to 0.76% of the DM) and other organic acids (other than caffeoylquinic and hydroxycinnamic acids and triterpenic acids) up to 0.27% (5.91% of the DM). Total phenolic compounds accounted for up to 0.61% of the additive (13.4% of the DM). The phenolic fraction included (i) flavonoids, (ii) hydroxycinnamic acid derivatives, (iii) phenolic diterpene derivatives, and (iv) shogaols. (i) Flavonoids amounted to up to 0.37% of the additive (8.18% of the DM), mainly luteolin glucuronides, (ii) caffeoylquinic and other hydroxycinnamic acid derivatives up to 0.30% of the additive (5.87% of the DM), (iii) phenolic diterpenes up to 0.08% of the additive (1.70% of the DM), and (iv) shogaols up to 0.012% (0.27% of the DM).

Despite uncertainties in the comparison of results obtained by different analytical methods, the FEEDAP Panel considers the fraction of total phenols (which includes flavonoids, hydroxycinnamic acids and their derivatives, phenolic diterpenes, and shogaols) sufficiently characterised. The volatile compounds accounted for up to 0.15% (w/w) of the tincture (0.14% on average).

The EFSA Compendium of botanicals²³ reports as substances of potential concern for human and animal health the occurrence of 1,8 cineole (22.01%–52.2%), camphor (7.57%–10.08%), L-piperitone (6.68%), myrcene (1.63%–2.61%), and verbenone (23.55%) in the essential oil from the aerial parts of *R. officinalis*. The presence of the diterpenes carnosic acid (16.9%), carnosol (1.93%), methyl carnosate (≥ 5.2%), and rosmanol (0.6%–3.9%) was reported in preparations extracts obtained by supercritical gas fluid extraction from the leaves of *R. officinalis*.

The applicant carried out an extensive literature search on the chemical composition of *R. officinalis* and its botanical preparations and the possible presence of substances of concern.²⁴ Several cumulative databases (including LIVIVO, NCBI, OVID, and ToxInfo) were searched. The keywords used covered different aspects of safety, and the inclusion and exclusion criteria were provided by the applicant. The literature search (no time limits specified) retrieved 67 references investigating the composition of preparations from *R. officinalis*. The results of the literature search confirmed the information in the EFSA Compendium. In addition, a few publications reported the presence of 0.9%–2.0% methyleugenol (Hazarika et al., 2020; Song et al., 2023) and 0.13% estragole (Dolghi et al., 2022; Moussii et al., 2020) in essential oils from *R. officinalis*. No other substances of concern were identified in the literature provided by the applicant.

3.3.1.1 | Impurities

The data provided by the applicant on the impurities²⁵ of the additive is reported in Table 3.

²²For each batch, the values analysed expressed as µg/mL were converted into g/100 g and given in % (w/w) of the additive considering the value of the density determined for each individual batch. The values expressed as % of the additive are then related to the DM content determined in the corresponding batch and expressed as % of the DM. The values reported in the text are the average and the highest value of the range calculated for the five batches.

²³Online version: <https://www.efsa.europa.eu/en/data-report/compendium-botanicals>, accessed on 15 May 2025.

²⁴Technical dossier/Supplementary information December 2024/Literature search_rosemary.

²⁵Technical dossier/Supplementary information December 2024/Rosemary tincture FFAC/Annex I_Rosemary tincture_Proximate analysis and impurities.

TABLE 3 Data on impurities of rosemary tincture A.

Parameter	Analysis	
	Range	No. of batches
Impurities		
Lead (mg/kg)	0.017–0.024	3
Mercury (mg/kg)	< 0.002	3
Cadmium (mg/kg)	< 0.002–0.0092	3
Arsenic (mg/kg)	0.028–0.094	3
Dioxins and furans (upper bound) ^a		
PCDD/Fs (ng WHO ₂₀₀₅ -TEQ/kg)	0.0855	3
PCDD/Fs + PCBs (ng WHO ₂₀₀₅ -TEQ/kg)	0.0986	3
Mycotoxins		
Aflatoxin B ₁ (µg/kg)	< 0.2	3
Ochratoxin A (µg/kg)	< 0.0005	3
Deoxynivalenol (µg/kg)	< 0.01	3
Zearalenone (µg/kg)	–	3
Fumonisin B1, B2 (µg/kg)	< 0.01	3
Patulin (µg/kg)	< 5	3
Citrinin (µg/kg)	< 0.01	3
Sterigmatocystin (µg/kg)	< 0.002	3
Pesticides (mg/kg)	< LOD ²	3
Diethyltoluamide (DEET) (mg/kg)	0.13–0.34	3
Microbial contamination		
Salmonella spp. (per 25 g)	Not detected	5
Escherichia coli (per g)	Not detected	5
Enterobacteriaceae (CFU/g)	< 10	5

Abbreviations: <, means below the limit of quantification; CFU, colony-forming unit; DM, dry matter; PCBs, polychlorinated biphenyls; PCDDs, polychlorinated dibenzo-*p*-dioxins; PCDFs, polychlorinated dibenzofurans; nDL-PCBs, non-dioxin-like PCBs; TEQ, toxic equivalent factors for dioxins, furans, and dioxin-like PCBs established by WHO in 2005 (Van den Berg et al., 2006); WHO, World Health Organization.

¹Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. Values are expressed per kg of additive with 88% dry matter content.

²For pesticides, a multiresidue analysis was provided, with LOD in a range of 0.05–0.15 mg/kg.

The FEEDAP Panel considers that the level of microbial contamination and detected impurities do not raise safety concerns.

3.3.1.2 | Shelf-life

The applicant states that the typical shelf-life of tincture A is at least 12 months when stored in tightly closed containers under standard conditions. However, no data supporting this statement was provided.

3.3.1.3 | Conditions of use

Rosemary tincture A is intended for use in feed for chickens for fattening, laying hens, horses, and dogs at a maximum proposed use level of 500 mg/kg complete feed.

3.3.2 | Characterisation of tincture B

Tincture B is a brown liquid, with a characteristic camphor odour. It has an average density of 1.05 kg/m³ (1.05 kg/m³) and a pH of 4.5 (4.5).²⁶

Table 4 summarises the results of the proximate analysis of five batches of the additive.²⁷ The solvent represents on average 98.72% of the additive, leaving a dry matter (DM) content of 1.28%. The DM consists of inorganic material measured as ash (14.6%) and a plant-derived organic fraction of 85.4%, which includes proteins, lipids, and ‘carbohydrates+fibres’.

²⁶Technical dossier/Supplementary information December 2024/Annex_II_4_Results of analysis.
²⁷Technical dossier/Supplementary information December 2024/Section II_Identity and Annex_II_4_Results of analysis.

‘Carbohydrates+fibres’ is the fraction obtained after subtracting the values for proteins and lipids from the organic fraction and contains a variety of plant-derived compounds, including phenolic compounds (see Table 4), in addition to any carbohydrate present.

TABLE 4 Proximate analysis of a rosemary tincture B, based on the analysis of five batches.

Constituent	Mean	Range
	% (w/w)	% (w/w)
Dry matter	1.28	1.20–1.39
Ash	0.19	0.17–0.20
Organic fraction	1.09	1.03–1.20
Proteins	< 0.08	< 0.08
Lipids	0.025	0.008–0.062
‘Carbohydrates+ fibres’ ¹	0.99	0.92–1.11
Solvent	98.72	98.61–98.80

¹‘Carbohydrates+fibres’ (by difference) include secondary plant metabolites, such as phenolic compounds.

The fraction of secondary metabolites was characterised in the same five batches of rosemary tincture B and the results are summarised in Table 5. The tincture was shown to contain polyphenols (0.200% on average, w/w) determined by spectrophotometry (at 760 nm) and expressed as gallic acid equivalents (GAE).²⁸ 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). Five unidentified peaks (corresponding to flavones and flavonols, flavonones phenolic acids) were detected by high-performance thin layer chromatography (HPTLC) and also expressed as GAE.²⁹ Rosmarinic acid (0.016% on average, w/w) was quantified by high-performance liquid chromatography (HPLC) with ultraviolet (UV) detection.³⁰ The concentrations of camphor,³¹ 1,8-cineole [03.001] and pulegone were determined by GC-FID in the same five batches of the tincture.³² Pulegone was below the limit of quantification (LOQ, 0.30 mg/kg, corresponding to less than 0.00003%) in all batches.

TABLE 5 Characterisation of the fraction of secondary metabolites of rosemary tincture B, based on the analysis of five batches (mean and range).

Constituent	CAS No	Mean	Range
		µg/mL	µg/mL
Total polyphenols ^{1,2}	–	1947	1828–2038
Rosmarinic acid	20283-92-5	157.2	137.2–177.5
Camphor ³	76-22-2	0.93	0.68–1.14
1,8-Cineole	470-82-6	3.71	2.76–4.54

Abbreviations: CAS no, Chemical Abstracts Service number.

¹Expressed as gallic acid equivalents (GAE).

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

³Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers is not given.

A comparison of the composition of the two tinctures under assessment is presented in Section 3.4 (Table 6). The applicant consulted the EFSA Compendium on botanicals (see Section 3.3.1) and made a literature search on the chemical composition of rosemary (*R. officinalis*) and its botanical preparations and the possible presence of substances of concern,³³ the results of which confirmed the information in the EFSA Compendium. In addition, other publications were identified which reported the presence of methyleugenol (0.1%–1.46%) in essential oils and other preparations from *R. officinalis* of different geographical origin (e.g. Ibáñez et al., 1999; Satyal et al., 2017; Tomi et al., 2016). The result of the literature search also indicated that, apart from the compounds identified in Table 5, rosemary extracts are rich in flavonoids (mainly luteolin derivatives), hydroxycinnamic acid derivatives (e.g. caffeic acid, chlorogenic acid), phenolic

²⁸Technical dossier/Supplementary information December 2024/Section_II_Identity and Annex_II_4_Results of analysis.

²⁹Technical dossier/Supplementary information December 2024/ Annex II_9_Detailed report of rosemary HPTLC analysis.

³⁰Technical dossier/Supplementary information December 2024/Annex II_7_CoA of rosmarinic acid in Rosmarinus officinalis tincture.

³¹Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given.

³²Technical dossier/Supplementary information December 2024/ Annex II_7_CoA of 1,8-cineole, camphor, and pulegone in rosemary tincture.

³³Technical dossier/Supplementary information December 2024/Annex II_5_Bibliographic data concerning chemical composition of rosemary and its extracts.

diterpenes (e.g. rosmanol and carnosol derivatives), triterpenes (e.g. betulinic acid, ursolic acid, micromeric acid), shogaols and other organic acids (e.g. quinic acid). This is in line with the analytical data provided for the characterisation of tincture A (see Table 2). No other substances of concern were identified in the literature provided by the applicant.

3.3.2.1 | Impurities

The applicant controls contamination at the level of the raw materials, including knowledge of the cultivation conditions and pesticides applied. Specifications are set with suppliers covering cadmium, mercury, lead and arsenic, fluorine, myco-toxins, pesticides, dioxins and polychlorinated biphenyls (PCBs) and microbial contamination.³⁴ An example of a quality control certificate of the raw material was provided.

The applicant stated that the 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.

3.3.2.2 | Shelf-life

The shelf-life of tincture B 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.

3.3.2.3 | 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 rosemary tincture B/kg complete feed for all animal species. No use level has been proposed for the use of rosemary tincture B in water for drinking.

3.4 | Safety

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

Table 6 shows a comparison of the two tinctures in terms of the percentage of ethanol in the extraction mixture, the plant:solvent ratio, the dry matter content of the tincture, the content of total polyphenols (determined by spectropho-tometry and expressed as GAE), of rosmarinic acid and of the volatile components, camphor and 1,8-cineole.

TABLE 6 Comparison of tinctures A and B.

	Tincture A	Tincture B	Ratio A:B
Ethanol % (v/v)	60	■	■
Plant:solvent ratio	1:5	■	–
Dry matter (% w/w)	4.25–4.56	1.2–1.39	3.3–3.5
Total phenolic compounds (µg/mL, as GAE)	4960–5617	1828–2038	2.71–2.76
Rosmarinic acid (µg/mL)	1997–2429	137.2–177.5	13.7–14.7
Camphor (µg/mL)	205–329	0.68–1.14	289–301
1,8-Cineole (µg/mL)	587–647	2.76–4.54	142–212

Abbreviations: GAE, gallic acid equivalents.

Because of the lower plant:solvent ratio, tincture B is more diluted than tincture A. This is reflected in the dry matter, which is 3.5-time lower for tincture B compared to tincture A (Table 6). The comparison between the analytical values available for the two tinctures shows that the impact of the water/ethanol composition of the extraction solvent on the content of flavonoids (mainly luteolin derivatives, accounting for a large fraction of total phenolic compounds in tincture A) is limited, whereas the extraction of hydroxycinnamic acid derivatives increases with increasing ethanol concentrations of the solvent as shown by Reichling et al. (2008). This is reflected by comparison of the concentrations of rosmarinic acid in the two tinctures. The rosmarinic acid concentration in tincture A is about 16-time higher compared to tincture B, which is the result of a 3.5-time higher concentration of dry matter and a 2.4-time higher ethanol content in tincture A compared to tincture B. Although the individual compounds present in the dry matter fraction of tincture B were not identified, it can be assumed that the qualitative composition of secondary metabolites in both tinctures should be similar. Because of the higher degree of dilution, the concentration of the individual compounds in tincture B should be lower compared

³⁴Technical dossier/Supplementary information December 2024/Annex II_1_Rosemary leaves description from plant supplier and CoA.

to tincture A. Therefore, it is assumed that the highest concentrations of flavonoids, phenolic diterpenes and derivatives, shogaols, triterpenes, other organic acids and volatile components in tincture A (see Table 2) are not exceeded in tincture B. In the absence of analytical data on the concentration of individual components or groups of components in tincture B, in a worst-case scenario, it is assumed that the same components identified and quantified in tincture A are present in tincture B at the same concentrations as in tincture A. Consequently, the FEEDAP Panel applies read-across from tincture A to tincture B for the evaluation of the safety for the target species, the consumer, the user, and the environment.

The tincture includes ash, proteins, lipids, and carbohydrates, which are not of concern and are not further considered. Among the secondary metabolites identified in rosemary tincture A, up to 0.61% (w/w) consisted of phenolic compounds. Within the phenolic fraction, flavonoids, caffeoylquinic and other hydroxycinnamic acid derivatives, phenolic diterpenes and shogaols were identified and quantified individually. The additive also contains ‘other organic acids’, triterpenes and volatile compounds (see Section 3.3.1).

Simple phenols and non-phenolic organic acids, including quinic acid and shikimic acid, caffeoylquinic acids and other hydroxycinnamic acid derivatives, are ubiquitous in food and feeds of plant origin. They will be 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, with the exception of rosmarinic acid, which is a characteristic and major component of the tinctures.

The tincture contains flavonoids, mainly glucuronides of luteolin and apigenin. For the ADME and the toxicology of flavonoids, reference is made to the safety evaluation made by the FEEDAP Panel in the EFSA opinion on bitter orange extract (EFSA FEEDAP Panel, 2021b). The tincture also contains phenolic diterpenes (carnosic acid derivatives), triterpenes and low concentrations of shogaols. For shogaols, reference is made to the opinion on ginger oleoresin and tincture (EFSA FEEDAP Panel, 2020a).

Twenty-five volatile constituents of rosemary tincture A have been already assessed as chemically defined flavourings for use in feed and food by the FEEDAP Panel and the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), the EFSA Panel on Food Additives and Flavourings (FAF) and/or by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The flavouring compounds, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000,³⁵ and the corresponding EFSA opinion are listed in Table 7. 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 by EFSA for use in food and feed. *d*-Camphor is therefore included in Table 7.

TABLE 7 Flavouring components of tincture A 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
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	Oct-1-en-3-ol	02.023	2020b
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a, 2020c
		α-Terpineol	02.014	2012a
		4-Terpinenol	02.072	
07	Primary alicyclic saturated and unsaturated alcohols/aldehydes/acids/acetals/esters with esters containing alicyclic alcohols	1,3-p-Menthadien-7-al ¹ (α-terpinen-7-al)	05.133	WHO (2010a, 2010b) (JECFA)
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	<i>d,l</i> -Borneol	02.016	2016a
		<i>d,l</i> -Fenchyl alcohol	02.038	
		<i>d</i> -Camphor ²	07.215	2016a, 2023b
		Pin-2-en-4-one ¹ (Verbenone)	07.196	2012, CEF
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012b, 2021a
23	Benzyl alcohols, aldehydes, acids, esters and acetals	4-Isopropylbenzyl alcohol	02.039	2012c
25	Phenol derivatives containing ring-alkyl, ring-alkoxy and side-chains with an oxygenated functional group	Thymol	04.006	2012d
		Carvacrol	04.031	

³⁵Commission 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 7 (Continued)

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA/JECFA opinion*, Year
30	Miscellaneous substances	Methyl 3-oxo-2-pent-2-enyl-1-cyclopentylacetate (methyl jasmonate) ³	09.521	WHO, 2005 (JECFA)
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	1-Isopropyl-4-methylbenzene (<i>p</i> -cymene)	01.002	2015
		α -Phellandrene	01.006	
		α -Terpinene	01.019	
		γ -Terpinene	01.020	
		Pin-2(10)-ene (β -pinene)	01.003	
		Pin-2(3)-ene (α -pinene)	01.004	2016b
		β -Caryophyllene	01.007	
		Myrcene	01.008	
		Camphene	01.009	2011, CEF
		3,7,10-Humulatriene ^{1,4}	01.043	
32	Epoxides	β -Caryophyllene epoxide ¹	16.043	2014, CEF

*FEEDAP opinion unless otherwise indicated.

¹Evaluated 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.

²Camphor is present in the additive as a mixture of enantiomers (*d,l*-camphor, the ratio between *d*- and *l*-stereoisomers is not given). EFSA evaluated *d*-camphor [07.215] for use in food (AFC Panel, 2008) and feed (EFSA FEEDAP Panel, 2016a).

³(*trans*)-(1*R*,2*R*)-(2*Z*)-isomer also called (–)-Methyl jasmonate (84%–97%). Other constituents are *trans*-(2*E*)-isomer (2%–8%) and *cis*-(2*Z*)-isomer (3%–8%). Total purity (sum of 3 main isomers): 98%–99%. EFSA evaluated methyl dihydrojasmonate [09.520] in CG 8 (EFSA FEEDAP Panel, 2016a).

⁴Evaluated 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.

With the exception of 3,7,10-humulatriene [01.043],³⁶ the 24 remaining components of rosemary tincture listed in Table 7 are considered safe for use as flavourings. They are currently authorised for use in food³⁷ without limitations and for use in feed³⁸ at individual use levels higher than those resulting from the intended use in feed of the additive under assessment. *d*-Camphor [07.147] and *d,l*-borneol [02.016] were included in tolerance studies made with the mixture of flavourings referred to as ‘Herbal’ (EFSA FEEDAP Panel, 2023b). Linalool [02.013] was similarly tested in the mixture of flavourings named ‘TuttiFrutti’ (EFSA FEEDAP Panel, 2020c). Based on these studies, the FEEDAP Panel concluded that *d,l*-borneol [02.016] is safe at 15 mg/kg complete feed for all animal species, *d*-camphor [07.147] at 5 mg/kg complete feed, and linalool [02.013] at 30 mg/kg complete feed. The FEEDAP Panel considered that the conclusions reached for *d*-camphor [07.147] can be extrapolated to the mixture of isomers of camphor by applying read-across (EFSA FEEDAP Panel, 2023b).

3.4.1 | Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals with the tinctures under application were not submitted. In the absence of these data, the approach to the safety assessment of the mixture is based on its individual components or groups of components (assessment groups). The combined toxicity can be predicted using the dose addition assumption within an assessment group (EFSA Scientific Committee, 2019a).

Camphor and *d,l*-borneol [02.016] are assessed separately based on the results of the tolerance studies carried out with the mixture of flavourings ‘Herbal’ (EFSA FEEDAP Panel, 2023b). Similarly, linalool [02.013], which was included in tolerance studies with the mixture of flavourings ‘TuttiFrutti’ (EFSA FEEDAP Panel, 2020c), is assessed separately.

For most other individual volatile components (Table 7) and for rosmarinic acid (Lasrado et al., 2015), subchronic oral toxicity studies are available, from which no observed adverse effect levels (NOAELs) were identified.

For the group assessment of flavonoids, phenolic diterpenes and their derivatives, shogaols and triterpenes, group NOAELs were identified from subchronic oral toxicity studies (EFSA FEEDAP Panel, 2020a, 2021b) or, in the absence of data, the threshold of toxicological concern (TTC) is applied (EFSA FEEDAP Panel, 2017b).

³⁶3,7,10-Humulatriene [01.043] has been evaluated in Flavouring Group Evaluations 25 Revision 2 by applying the procedure described in the Guidance on the data required for the risk assessment of flavourings to be used in or on foods (EFSA CEF Panel, 2010). For this compound, for which there is no concern for genotoxicity, EFSA requested additional subchronic toxicity data (EFSA CEF Panel, 2011). In the absence of these data, the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015a). As a result, this compound is no longer authorised for use as flavours in food.

³⁷Commission 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.

³⁸European 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.

3.4.1.1 | Components tested in tolerance trials with mixtures of flavourings

At the maximum proposed use level of 500 mg rosemary tincture A/kg complete feed and considering the highest analysed concentration of camphor³⁹ (0.036%) in the tincture, the corresponding level of camphor in complete feed would be 0.178 mg/kg. This concentration is well below the concentration of 5 mg *d*-camphor/kg complete feed considered safe for all animal species when tested in tolerance studies with the mixture 'Herbal' (EFSA FEEDAP Panel, 2023b). Therefore, no concern for the target species is expected from the presence of camphor in rosemary tincture A.

The highest concentrations in feed of *d,l*-borneol [02.016] resulting from the use of the additive at the maximum proposed use level of 500 mg tincture A/kg complete feed would be 0.050 mg/kg complete feed.⁴⁰ This concentration is below the safe level of 15 mg/kg complete feed established for all animal species based on the results of the tolerance trials with the mixture of flavourings 'Herbal' (EFSA FEEDAP Panel, 2023b).

The highest concentrations in feed of linalool [02.013] resulting from the use of the additive at the maximum proposed use level of 500 mg tincture A/kg complete feed would be 0.011 mg/kg complete feed.⁴¹ This concentration is below the safe level of 30 mg/kg complete feed established for all animal species based on the results of the tolerance trials with the mixture of flavourings 'TuttiFrutti' (EFSA FEEDAP Panel, 2020c).

3.4.1.2 | Components other than those tested in tolerance trials: Flavonoids, rosmarinic acid, phenolic diterpenes, shogaols, triterpenes and volatile components

The safety assessment is based on the different classes of compounds present in rosemary tincture A: flavonoid derivatives, rosmarinic acid, phenolic diterpenes, shogaols, triterpenes and volatile compounds.

Based on considerations related to structural and metabolic similarities, flavonoids were allocated to the same assessment group. Based on similar considerations, other assessment groups included phenolic diterpenes (carnosic acid derivatives), shogaols or triterpenes.

The volatile compounds present in tincture A were allocated to nine assessment groups, corresponding to the chemical groups (CGs) 5, 6, 8, 16, 23, 25, 30, 31 and 32, as defined in Annex I of Regulation (EC) No 1565/2000. For CG 31 (aliphatic and aromatic hydrocarbons), sub-assessment groups as defined in Flavouring Group Evaluation 25 (FGE.25) and FGE.78 were established (EFSA CEF Panel, 2015a, 2015b). The allocation of the components to the (sub-)assessment groups is shown in Table 8 and in the corresponding footnote.

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 2018⁴²). 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 was assessed to explore the application of read-across, allowing extrapolation from a known NOAEL of a component of an assessment group to the other components of the same group with no available NOAEL or, if sufficient evidence were available for members of a (sub-)assessment group, to derive a (sub-)assessment group NOAEL.

For flavonoids, the FEEDAP Panel identified a NOAEL of 500 mg/kg bw per day for hesperidin, which was applied as a group NOAEL to all the flavanones and flavones present in bitter orange extract (EFSA FEEDAP Panel, 2021b). Considering the structural and metabolic similarities within the assessment group of flavonoids, the FEEDAP Panel applies the same NOAEL to all the flavonoids present in rosemary tincture A at very low concentrations.

For rosmarinic acid, a NOAEL of 300 mg/kg bw per day was identified from a 90-day study in rats with spearmint extract containing 15.4% rosmarinic acid (doses: 0, 422, 844 and 1948 mg spearmint extract/kg bw per day, corresponding to 0, 65, 130 and 300 mg rosmarinic acid/kg bw per day). No effects were observed up to the highest dose tested (Lasrado et al., 2015).

For carnosic acid derivatives, the applicant provided a reference to a subchronic toxicity study in rats with a rosemary extract containing 33.3% of a mixture of carnosol and carnosic acid from which a NOAEL of 64 mg/kg bw per day could be identified (Phipps et al., 2021). Considering the structural and metabolic similarities within the assessment group of phenolic diterpenes and their derivatives, the FEEDAP Panel applies the same NOAEL to all carnosic acid derivatives present in rosemary tincture A at very low concentrations.

From a 35-day toxicity study in rats with ginger rhizome powder (containing 9.1 mg/kg of 6-gingerol and 1.6 mg/kg of 6-shogaol), a NOAEL of 11 mg/kg bw per day (corresponding to 1000 mg/kg bw of ginger rhizome) was identified for the sum of gingerols and shogaols based on a reduction of absolute and relative weights of testes observed at the highest dose (EFSA FEEDAP Panel, 2020a). In the current assessment, the NOAEL of 11 mg/kg bw per day is applied to shogaol derivatives.

For triterpenes, the applicant provided several references from the literature which indicated that the NOAEL > 1000 mg/kg bw per day for oleanolic acid (Gupta & Singh, 2024), betulinic acid (Farsi et al., 2016) and ursolic acid (Geerlofs et al., 2020; Jung et al., 2025). Considering the structural and metabolic similarities within the assessment group, the FEEDAP Panel applies a group NOAEL of 1000 mg/kg bw per day to all triterpene derivatives present in rosemary tincture A.

³⁹Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given.

⁴⁰Calculated considering the maximum proposed use level of 500 mg/kg complete feed and the highest concentration of *d,l*-borneol (0.010%) in the five batches.

⁴¹Calculated considering the maximum proposed use level of 500 mg/kg complete feed and the highest concentration of linalool (0.002%) in the five batches.

⁴²Toxtree 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/>.

For the volatile components of the tincture, sub-chronic studies from which NOAEL values could be identified were available for the following components or for structurally related compounds: 37 mg/kg bw per day for deca-2(*trans*), 4(*trans*)-dienal [05.140] in CG 3 (EFSA FEEDAP Panel, 2019b), 6.7 mg/kg bw per day for oct-1-en-3-one [07.081] in CG 5 (EFSA FEEDAP Panel, 2020b), 250 mg/kg bw per day for terpineol [02.230]⁴³ in CG 6 (EFSA FEEDAP Panel, 2012a), 100 mg/kg bw per day for 1,8-cineole [03.001] in CG 16 (EFSA FEEDAP Panel, 2021a), 44 mg/kg bw per day for myrcene [01.008], 154 mg/kg bw per day for *p*-cymene [01.002] and 222 mg/kg bw per day for β -caryophyllene [01.007] in CG 31 (EFSA FEEDAP Panel, 2015, 2016b) and 109 mg/kg bw per day for β -caryophyllene epoxide [16.043] in CG 32 (EFSA CEF Panel, 2014). For α -terpinene [01.019], the FEEDAP Panel identified a NOAEL of 60 mg/kg body weight (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). The NOAEL of 60 mg/kg bw per day was divided by a factor of 2 to take into account of the nature of the study.

In its assessment of CG 3, the FEEDAP Panel applied the NOAEL of 34 mg/kg bw per day for deca-2(*trans*), 4(*trans*)-dienal [05.140] to all linear compounds sharing the same 2-*trans*, 4-*trans*-dienal structure (EFSA FEEDAP Panel, 2019b). In line with the assessment done by JECFA (WHO, 2010a, 2010b), the FEEDAP Panel considers that the same NOAEL could be applied to 1,3-*p*-menthadien-7-al [05.133], a cyclic compound sharing the same 2-*trans*, 4-*trans*-dienal structure. This NOAEL was selected as a group NOAEL for CG 7 compounds (EFSA FEEDAP Panel, 2022).

In CG 5, the NOAEL of 6.7 mg/kg bw per day for oct-1-en-3-one [07.081] was applied to oct-1-en-3-ol [02.023] (EFSA FEEDAP Panel, 2020a, 2020b, 2020c).

In CG 6, a NOAEL of 250 mg/kg bw per day was identified for terpineol [02.230] and divided by a factor of 2 to take into 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 8, the benchmark dose lower confidence limit for a benchmark response of 10% (BMDL₁₀) of 60 mg/kg bw per day for *d*-carvone (EFSA Scientific Committee, 2014) was applied to the structurally related ketone verbenone [07.196].

Considering the structural and metabolic similarities, the NOAEL for the representative compound in CG 31,V, β -caryophyllene [01.007] was applied using read-across to the compounds α -pinene [01.004], β -pinene [01.003] and camphene [01.009]⁴⁴ (EFSA CEF Panel, 2015a). The NOAEL of 222 mg/kg bw per day for β -caryophyllene [01.007] was also applied to *cis*-sabinene hydrate in CG 6, 14-hydroxycaryophyllene in CG 8 and 3,7,10-humulatriene [01.043] in CG 31,VI. For 3,7,10-humulatriene, the NOAEL of β -caryophyllene was divided by a factor of 2 to take into account of the uncertainty in read-across due to differences in the structure (extrapolation from a tricyclic to a macrocyclic non-aromatic compound) (EFSA FEEDAP Panel, 2023c).

For the remaining compounds, fenchyl alcohol [02.038] and methyl 3-oxo-2-pent-2-enyl-1-cyclopentylacetate [09.521], toxicity studies were not available, and read-across was not possible. Therefore, the 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 mg/kg bw per day for Cramer Class I compounds, Munro et al., 1996). Reference points selected for each compound are shown in Table 8.

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 levels of 500 mg rosemary tincture A/kg complete feed, the percentage of the component in the oil and the default values for body weight and feed intake according to the guidance on the safety of feed additives for target species (EFSA FEEDAP Panel, 2017b). For 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 an assessment group, (i) when a group reference point is available, a group MOE was calculated for the combined intake; (ii) when different reference points are available for the components, the combined (total) margin of exposure (MOET) was calculated as the reciprocal of the sum of the reciprocals of the MOE for the individual substances (EFSA Scientific Committee, 2019a). An MOE(T) > 100 allowed for interspecies differences and intra-individual variability. The volatile 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.⁴⁵

The approach to the safety assessment of rosemary tincture A is shown in Table 8 for chickens for fattening, which is the species with the highest ratio of feed intake/body weight and represents the worst-case scenario among the target species.

⁴³Terpineol 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.

⁴⁴Some of these compounds are not listed in Table 4 because their individual margin of exposure (MOE) was > 50,000.

⁴⁵Compounds included in the assessment groups but not reported in the table: oct-1-en-3-ol (CG 5); 4-terpinenol (CG 6); 1,3-*p*-menthadien-7-al (CG 7); *cis*-sabinene hydrate, fenchyl alcohol, 14-hydroxycaryophyllene, verbenone (CG 8); 4-isopropylbenzyl alcohol (CG 23); carvacrol (CG 25); myrcene, α -phellandrene, α -terpinene, γ -terpinene (CG 31, II); *p*-cymene (CG 31, IVe); β -caryophyllene, α -pinene, camphene β -pinene (CG 31, V); 3,7,10-humulatriene (CG 31, VI); β -caryophyllene epoxide, humulene oxide II (CG 32).

TABLE 8 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 rosemary tincture A classified according to assessment groups and combined margin of exposure (MOET) for each assessment group.

Tincture composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group		Highest concentration in the tincture	Highest concentration in feed	Intake ¹	Cramer class ²	NOAEL ³	MOE ⁴	MOET ⁵
Constituent	–	(µg/mL)	mg/kg	mg/kg bw	–	mg/kg bw	–	–
Flavonoids								
Luteolin 3'-o-glucuronide		1414.8	0.766	0.0688	(III)	500	7267	
Luteolin-3'-O-β-D-glucuronic- acid-6''-methyl ester		396.8	0.215	0.0193	(III)	500	25,908	
Luteolin-3'-acetylglucuronide (Isomer I or II)		542.8	0.294	0.0264	(III)	500	18,943	
Nepitrin		212.3	0.115	0.0103	(III)	500	48,477	
Luteolin-7-glucuronide		164.0	0.089	0.0080	(III)	500	62,700	
Luteolin-3'-acetylglucuronide (Isomer I or II)		255.4	0.138	0.0124	(III)	500	40,261	
Luteolin derivative		94.5	0.051	0.0046	(III)	500	108,776	
Genkwanin		84.7	0.046	0.0041	(III)	500	121,576	
Homoplantaginin		85.3	0.046	0.0041	(III)	500	120,576	
Cirsimaritin		63.5	0.034	0.0031	(III)	500	162,038	
Flavone 5 (genkwanin derivative)		37.9	0.021	0.0018	(III)	500	271,646	
Flavone 1 (apigenin derivative)		38.0	0.021	0.0018	(III)	500	270,780	
Flavone 3		19.8	0.011	0.0010	(III)	500	515,414	
Acacetin		25.2	0.014	0.0012	(III)	500	407,835	
Flavone 4 (quercetin derivative)		18.3	0.010	0.0009	(III)	500	559,399	
Apigenin		20.7	0.011	0.0010	(III)	500	496,212	
6''-O-(E)-Feruoyl-homoplantaginin		14.8	0.008	0.0007	(III)	500	693,760	
Flavone 2 (apigenin derivative)		12.4	0.007	0.0006	(III)	500	830,723	
Group MOE flavonoids							2937	
Hydroxycinnamic acid derivatives								
Rosmarinic acid		2429	1.315	0.1181	(III)	300	2541	
Phenolic diterpenes (Carnosic acid derivatives)								
Methyl Carnosate		368.2	0.199	0.0179	(I)	64	3578	
Epirosmanol-ethylether		213.1	0.115	0.0104	(III)	64	6177	
Rosmanol-ethylether		78.8	0.042	0.0038	(III)	64	16,967	
Carnosol		99.7	0.054	0.0048	(III)	64	13,196	
Rosmanol		25.5	0.014	0.0012	(III)	64	51,629	
12-Methyl-carnosol		10.7	0.005	0.0005	(III)	64	132,445	
5,6,7,10-tetra-hydro-7-OH-Rosmariquinone		8.0	0.004	0.0004	(III)	64	176,319	
Epirosmanol		5.7	0.003	0.0003	(III)	64	249,268	
Epiisorosmanol		1.8	0.001	0.0001	(III)	64	731,922	
Other decomposition product of carnosol		31.2	0.016	0.0015	(III)	64	43,380	
Group MOE phenolic diterpenes							1845	
Shogaols								
Shogaol-like compound 1		82.8	0.045	0.0041	(I)	11	2716	
Shogaol-like compound 2		25.9	0.014	0.0013	(I)	11	8740	
Group MOE shoagaols							2122	
Triterpenes								
Betulinic acid		129.8	0.070	0.0063	(I)	1000	158,556	
Micromeric acid		105.4	0.057	0.0051	(III)	1000	195,021	

TABLE 8 (Continued)

Tincture composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group		Highest concentration in the tincture	Highest concentration in feed	Intake ¹	Cramer class ²	NOAEL ³	MOE ⁴	MOET ⁵
Oleanolic Acid		58.3	0.032	0.0028	(I)	1000	352,892	
Ursolic Acid		59.4	0.032	0.0029	(I)	1000	346,788	
Group MOE triterpenes							69,002	
Volatiles	FLAVIS-No							
CG 6								
α-Terpineol	02.014	86.3	0.047	0.0042	(I)	250	29,806	
CG 16								
1,8-Cineole	03.001	647.4	0.353	0.0317	(I)	100	3159	
CG 25								
Thymol	04.006	50.0	0.027	0.0024	(I)	36	14,725	
CG 30								
Methyl 3-oxo-2-pent-2-enyl-1-cyclopentylacetate	09.521	18.6	0.010	0.0009	II	<i>0.91</i>	1009	

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

¹Rounded intake values are shown in the Table intake/body weight.

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

³Values **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.

⁴The 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 used 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**.

⁵The 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. MOET values are reported **in bold**.

As shown in Table 8, for all assessment groups, the MOE(T) calculated for chickens for fattening at the maximum proposed use levels of tincture A in feed of 500 mg/kg was > 100. The lowest MOE of 1009 was calculated for the assessment group CG 30. The MOEs for CG 30 calculated for the other target species at 500 mg/kg complete feed are summarised in Table 9.

TABLE 9 Combined margin of exposure (MOET) for the assessment group CG 30 calculated for the different target animal categories at the proposed use level of rosemary tincture of 500 mg/kg complete feed.

Animal category	Daily feed intake (g DM/kg bw)	Use level (mg/kg complete feed) ¹	Lowest MOE CG 30
Chickens for fattening	79	500	1009
Laying hens	53	500	1504
Turkeys for fattening	59	500	1351
Pigs for fattening	44	500	1812
Piglets	37	500	2154
Sows lactating	30	500	2657
Veal calves (milk replacer)	19	500	4195
Cattle for fattening	20	500	3986
Dairy cows	31	500	2571
Sheep/goats	20	500	3986
Horses	20	500	3986
Rabbits	50	500	1594
Salmonids	18	500	4428
Dogs	17	500	4689
Cats ²	20	500	3986
Ornamental fish	5	500	15,942

Abbreviations: bw, body weight; DM, dry matter; MOE, margin of exposure.

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

²The MOET for cats is increased to 500 because of the reduced capacity of glucuronidation.

For all animal species and categories listed in Table 9, the MOE exceeds the value of 100. Because glucuronidation is an important metabolic pathway to facilitate the excretion of the components of the essential oil and considering that cats have an unusually low capacity for glucuronidation, particularly for aromatic compounds (Court and Greenblatt, 1997; Lautz et al., 2021), the use of rosemary oil as an additive in cat feed needs a wider margin of exposure. A MOE of 500 is considered adequate. Therefore, no safety concern was identified for rosemary tinctures, when used as a feed additive at the proposed use level of 500 mg/kg complete feed. These conclusions are extrapolated to all animal species.

Use in water for drinking

The FEEDAP Panel considers that the use of tincture B in water for drinking is safe provided that the daily exposure via water or in combination with feed does not exceed the exposure resulting from the use in feed at the maximum use level (500 mg/kg).

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

The FEEDAP Panel concludes that the rosemary tinctures are safe at the maximum proposed use levels of 500 mg/kg complete feed:

- rosemary tincture A for chickens for fattening, laying hens, horses and dogs,
- rosemary tincture B for all animal species.

The FEEDAP Panel considers that, for tincture B, the use in water for drinking alone or in combination with use in feed should not exceed the daily amount that is considered safe when consumed via feed.

3.4.2 | Safety for the consumer

Rosemary leaves and their preparations, including ethanolic extracts, are added to a wide range of food categories as spice or for flavouring purposes. Although individual consumption figures for the EU are not available, Fenaroli's handbook of flavour ingredients (Burdock, 2009) cites values of 0.44 mg/kg bw per day for rosemary leaves and their extracts and 0.003 mg/kg bw per day for rosemary oil obtained from the fresh flowering tops.

No data on residues in products of animal origin were made available for any of the constituents of the tinctures. When considering the absorption, distribution, metabolism and excretion (ADME) of the individual components, the phenolic compounds, including flavonoids, rosmarinic acid, phenolic diterpenes and shogaols, present in the additive at low concentrations, will be readily metabolised and excreted and are not expected to accumulate in animal tissues and products. Similarly, for triterpenes and the volatile compounds present in the tincture, the available data indicate that they are absorbed, metabolised and rapidly excreted and are not expected to accumulate in animal tissues and products.

Considering the above and the reported human exposure due to the direct use of rosemary and its preparations in food (Burdock, 2009), it is unlikely that consumption of products from animals given rosemary tinctures A and B 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 rosemary tinctures 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 additives for users.

The applicant provided information according to Classification, Labelling and Packaging (CLP) Regulation (EC) 1272/2008⁴⁶ concerning the presence of ethanol in tinctures A and B.⁴⁷

Tinctures A and B contain camphor and 1,8-cineole, compounds for which hazards for skin and eye contact and respiratory exposure were recognised (EFSA FEEDAP Panel, 2012b, 2016a). The additives under assessment should be considered to be irritants to skin and eyes and to be a dermal and respiratory sensitiser. Any exposure is considered a risk.

3.4.4 | Safety for the environment

S. rosmarinus is a species native to Europe where it is widely grown both for commercial and decorative purposes. Therefore, the use of the rosemary tinctures A and B under the proposed conditions of use in animal feed is not expected to pose a risk to the environment.

⁴⁶Regulation (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.

⁴⁷Technical dossier/Supplementary information December 2024/Annex_XI_SIn reply_rosemary_tincture_MSDS.

3.5 | Efficacy

Rosemary (given as the synonym *R. officinalis*) and its oil are listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009), by the Flavour and Extract Manufacturers Association (FEMA) with the reference numbers 2991 (rosemary) and 2992 (rosemary oil).

Since rosemary and its 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 for rosemary tinctures A and B.

4 | CONCLUSIONS

The FEEDAP Panel concludes that the rosemary tinctures from *Salvia rosmarinus* Spenn (homotypic syn. *Rosmarinus officinalis* L.) are safe at the maximum proposed use level of 500 mg/kg complete feed:

- rosemary tincture A for chickens for fattening, laying hens, horses and dogs,
- rosemary tincture B for all animal species.

Only tincture B is also intended for use in water for drinking for all animal species. The FEEDAP Panel considers that, for tincture B, the use in water for drinking alone or in combination with use in feed should not exceed the daily amount that is considered safe when consumed via feed.

No concerns for consumers and the environment were identified from the use of rosemary tinctures A and B in animal feed.

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

Since *S. rosmarinus* 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. <i>Issues: analytical methods</i>
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 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. <i>Issues: characterisation, safety for target species, safety for the consumer, safety for the user and environment</i>
28/09/2023	Partial withdrawal of the application for the following additive: Spanish majoram oil
08/07/2024	Partial withdrawal of the application for the following additives: lilac chastetree extract and savory summer tincture
26/08/2024	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives. Partial report related to seven additives: Spanish sage oil, peppermint oil, thymus organum oil, patchouli oil, clary sage oil, lavender oil and sage oil
27/08/2024	Reception of supplementary information from the applicant (letter of agreement)
06/12/2024	Reception of supplementary information from the applicant (partial dataset: rosemary tinctures) - Scientific assessment remains suspended
16/12/2024	Partial withdrawal of the application for the following additives: devils claw extract (wb), balm leaves extract (sb), olive extract (sb)

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Date	Event
18/06/2025	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives. Partial report related to 11 additives: cornmint oil, spearmint oil, thyme oil, rosemary oil, marjoram oil, rosemary tincture, basil tincture, lavender tincture, peppermint tincture, sage tincture and wild thyme tincture.
26/06/2025	The application was split and a new EFSA-Q-2025-00404 was assigned to the additive included in the present assessment. Scientific assessment re-started for the additive included in the present assessment
16/09/2025	Opinion adopted by the FEEDAP Panel on rosemary tinctures (EFSA-Q-2025-00404). 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
DM	dry matter
EEIG	European economic interest grouping
EMA	European Medicines Agency
EU	European Union
EURL	European Union Reference Laboratory
FEMA	Flavour and Extract Manufacturers Association
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)
FLAVIS	The EU Flavour Information System
JECFA	Joint FAO/WHO Expert Committee of Food Additives
GAE	gallic acid equivalent
GC-FID	gas chromatography-flame ionisation detection
HACCP	Hazard Analysis and Critical Control Points
HPTLC	high performance thin layer chromatography
LOD	limit of detection
NOAEL	no observed adverse effect level
PhEur	European Pharmacopoeia
SC	EFSA Scientific Committee
WHO	World Health Organization

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REQUESTOR

European Commission

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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, Ilén Röhe, and Katerina Theodoridou.

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