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SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of an essential oil derived from the leaves of *Cymbopogon nardus* (L.) Rendle (citronella oil) for use in all animal species (FEFANA asbl)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of citronella oil obtained from the leaves of *Cymbopogon nardus* (L.) Rendle, when used as a sensory additive for all animal species. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that citronella oil from *C. nardus* is of low concern for long-living and reproductive animals at the use levels in complete feed of 3.5 mg/kg for laying hens and rabbits, 6 mg/kg for sows and dairy cows, 9.5 mg/kg for sheep/goats and horses, 2.0 mg/kg for cats and 10 mg/kg for dogs. For short-living animals (species for fattening), the additive was considered of no concern at concentrations of 18 mg/kg in chickens for fattening, 24 mg/kg in turkeys for fattening, 20 mg/kg for piglets, pigs for fattening, veal calves (milk replacer), cattle for fattening, sheep/goats for meat production, horses for meat production and rabbits for meat production, and 30 mg/kg for salmonids. The conclusions were extrapolated to physiologically related minor species. For any other species, the additive is considered of low concern at 2.0 mg/kg complete feed. The use of citronella oil in animal feed is expected to be of no concern for the consumers and for the environment. The essential oil under assessment should be considered as irritant to skin and eyes and as a dermal sensitiser. When handling the essential oil, exposure of unprotected users to methyleugenol may occur. Therefore, to reduce the risk, the exposure of the users should be minimised. Since the leaves of *C. nardus* and its preparations were recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy was considered necessary.

KEYWORDS

C. nardus, citronella oil, citronellal, efficacy, flavouring compounds, safety, sensory additives

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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 18 preparations (namely geranium oil, geranium rose oil, eucalyptus oil, eucalyptus tincture, clove oil, clove tincture, broom tea tree oil, purple loosestrife tincture, tea tree oil, melaleuca cajuputi oil, niaouli oil, allspice oil, bay oil, pomegranate bark extract, bambusa tincture, lemongrass oil, citronella oil and vetiveria oil) belonging to botanically defined group (BDG) 07 – Geraniales, Myrtales, Poales when used, when used as a feed additive for all animal species (category: sensory additives; functional group: flavourings). During the assessment, the applicant withdrew the application for six preparations (namely broom tea tree oil, geranium oil, bay oil and vetiveria oil;[3] bambusa tincture and allspice oil[4]). These preparations were deleted from the register of feed additives.[5] During the course of the assessment, this application was split, and the present opinion covers only one out of the remaining 12 preparations under application: citronella oil from the leaves of *Cymbopogon nardus* (L.) Rendle.[6]

The remaining 11 preparations belonging to botanically defined group (BDG) 07 – Geraniales, Myrtales, Poales 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 21 December 2010.

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 citronella oils from *C. nardus* (fresh or partly dried leaves), when used under the proposed conditions of use (see Section 3.2.4).

1.2 | Additional information

An essential oil from *C. nardus* (L.) W. Wats. 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[7] in support of the authorisation request for the use of citronella oil from *C. nardus* as a feed additive. The dossier was received on 26/3/2024 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2024-00190.[8]

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

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2]On 13/3/2013, EFSA was informed by the applicant that the applicant company changed to FEFANA asbl, Avenue Louise 130 A, Box 1, 1050 Brussels, Belgium.
[3]On 27 February 2019, EFSA was informed by the applicant about the withdrawal of the applications on broom tea tree oil, geranium oil, bay oil and vetiveria oil.
[4]On 18 November 2022, EFSA was informed by the European Commission about the withdrawal of the applications on bambusa tincture and allspice oil.
[5]Register of feed additives, Annex II, withdrawn by OJ L162, 10.5.2021, p. 5.
[6]Accepted name: *Cymbopogon nardus* (L.) Rendle; synonyms: *Cymbopogon nardus* (L.) W. Wats, *Cymbopogon nardus* (L.) Hook. f., *Cymbopogon nardus* (L.) W. Watson var. lenabatu Stapf.
[7]Dossier reference: FAD-2010-0219.
[8]The original application EFSA-Q-2010-01282 was split on 26/03/2024 and a new EFSA-Q-2024-00190 was generated.

Many of the components of the essential oils 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 07, including the current one under assessment.[9]

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the phytochemical markers in the additive. The evaluation report is related to the methods of analysis for each feed additive included in the group BDG 07 (Geraniales, Myrtales, Poales). During the assessment, upon request from EFSA, the EURL issued two amendments[10] of the original report. The additive under assessment, *citronella oil* from *C. nardus*, is included in the second amendment. In particular, the EURL recommended a method based on gas chromatography with flame ionisation detection (GC-FID) for the quantification of the phytochemical marker *citronellal* in citronella oil.[11]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of citronella oils from *C. nardus* is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance documents: Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA Scientific Committee, 2009), Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2012), Guidance 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, 2018), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023a), Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019a), Statement on the genotoxicity assessment of chemical mixtures (EFSA Scientific Committee, 2019b), Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Scientific Committee, 2019c) and General approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic (EFSA FEEDAP Panel, 2021a).[13]

3 | ASSESSMENT

The additive under assessment, citronella oil from *C. nardus* (L.) Rendle, is obtained from the fresh or partly dried leaves of the plant 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

C. nardus (L.) Rendle (citronella grass, Ceylon citronella) is a perennial grass species belonging to the family Poaceae. *C. nardus* is native to Africa and to tropical regions of Asia. It is now common to tropical regions where it grows to about 2 m in height. Like the related species, *Cymbopogon winterianus* Jowitt ex Bor. (Java citronella), *C. nardus* is used for the production of citronella oil, which is used to flavour food, in soaps, as an insect repellent in insect sprays and candles, and in aromatherapy. Besides oil production, citronella grass may also be used for culinary purposes as an alternative to lemongrass (e.g. *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson, *Cymbopogon citratus* Stapf.).

The essential oil is extracted by steam distillation from the fresh or partly dried leaves of *C. nardus*. The volatile constituents are condensed and then separated from the aqueous phase by decantation.

[9]Technical dossier/Supplementary information February 2023/Letter dated 31/1/2023.

[10]Preparations included in the first amendment: geranium rose oil, eucalyptus oil, lemongrass oil and clove oil; preparations included in the second amendment: citronella oil, melaleuca cajuputi oil, tea tree oil, clove tincture and eucalyptus tincture.

[11]The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0219_en.

[12]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.

[13]https://www.efsa.europa.eu/sites/default/files/2021-05/general-approach-assessment-botanical-preparations-containing-genotoxic-carcinogenic-compounds.pdf.

3.2 | Characterisation

3.2.1 | Characterisation of citronella oil

Citronella oil extracted from *C. nardus* is a clear, pale yellow to pale brownish yellow, liquid with a leafy and earthy odour. Citronella oil from *C. nardus* is identified with the single Chemical Abstracts Service (CAS) numbers 8000-29-1 and 89998-15-2,[14] the European Inventory of Existing Commercial Chemical Substances (EINECS) number 289-753-6, the Flavor Extract Manufacturers Association (FEMA) number 2308[15] and the Council of Europe (CoE) number 39.

For citronella oil from *C. nardus*, the product specifications used by the applicant are based on those developed by the International Organisation for Standardization (ISO) 3849:2003 for oil of citronella, Sri Lanka type [*C. nardus* (L.) W. Watson var. lenabatu Stapf.],[16] which were adapted to reflect the concentrations of selected volatile components. Five components contribute to the specifications as shown in Table 1, with citronellal selected as the phytochemical marker. The analysis of one batch of the additive showed compliance with the specification when analysed by GC-FID and expressed as percentage of gas chromatographic peak area (% GC area).[17] Analysis of four batches of the additive showed compliance with these specifications when analysed by gas chromatography–mass spectrometry (GC–MS), except for limonene [01.001] which was below the specification (Table 1).[18]

TABLE 1 Major constituents of the essential oil from the leaves (fresh or partly dried) of *Cymbopogon nardus* (L.) Rendle as defined by specifications: batch to batch variation based on the analysis of four batches by gas chromatography–mass spectrometry (GC–MS).

Constituent			% GC area		
EU register name	**CAS no**	**FLAVIS no**	**Specification[a]**	**Mean**	**Range**
Citronellal	106-23-0	05.021	3–6	4.61	3.92–5.12
Geraniol	106-24-1	02.012	15–23	17.22	16.17–18.33
Citronellol	106-22-9	02.011	3–8.5	4.37	3.95–4.57
Limonene	138-86-3	01.001	7–11.5	6.42	5.75–7.18
(*E*)-Methyl isoeugenol	93-16-3	04.013	7–15	12.13	9.89–13.89
Total				44.733	43.27–46.33[b]

Note: The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%.

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

[a]Specifications defined based on gas chromatography-flame ionisation detection (GC-FID) analysis.

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

The applicant provided the full characterisation of the volatile constituents in the same four batches obtained by GC–MS.[19] In total up to 104 constituents were detected, all of which were identified and accounted on average for 100% (99.9%–100.1%) of the % GC area. The five compounds indicated in the product specifications accounted for about 44.7% (range 43.3%–46.3%) of the % GC area (Table 1). Besides the five compounds indicated in the product specifications, 28 other compounds were detected at individual levels >0.5% and are listed in Table 2. These 33 compounds together accounted on average for 92.9% (range 91.9%–93.3%) of the % GC area. The remaining 71 compounds (ranging between 0.02 and 0.49%) and accounting on average for 7.1% of the % total GC area are listed in the footnote.[20] Based on the available data on the characterisation, citronella oil from *C. nardus* is considered a fully defined mixture (EFSA Scientific Committee, 2019a).

[14]CAS No. 8007-29-1 is applied to the essential oil from either *C. nardus* or *C. winterianus*. CAS No. 89998–15-2 covers all extracts of *C. nardus* obtained by steam distillation.

[15]FEMA 2308 referrers to citronella oil from *C. nardus* Rendle and *C. winterianus* Jowitt.

[16]Technical dossier/Supplementary information June 2023/Annex IV_SIn_reply_citronella_oil_ISO_3849:2003.

[17]Technical dossier/Supplementary information June 2023/EURL_appendix_citronella_oil. GC-FID analysis: citronellal (4.1%), geraniol (18.6%), citronellol (4.5%), limonene (7.6%) and (*E*)-methyl isoeugenol (14.9%).

[18]Technical dossier/Supplementary information June 2023 Annex_XI_SIn_reply_citronella_oil_composition, Annex_X_nardus.

[19]Technical dossier/Supplementary information June 2023/Annex_II_SIn_reply_citronella_oil_CoAs_chromatograms.

[20]Additional constituents: Constituents ($n=11$) between <0.5% and ≥0.2%: linalool, *trans*-3,7-dimethylocta-2,6-dienal, camphene hydrate, β-caryophyllene epoxide, 2,5-bornanediol, T-cadinol, epi-γ-eudesmol, isocarveol, sabinene hydrate, T-muurolol and 4-carene; constituents ($n=18$) between <0.2% and ≥0.1%: *p*-menth-1-en-3-one, neral, gamma-amorphene, geranyl hexanoate, β-bourbonene, isoborneol, neoisoisopulegol, linalyl formate, *o*-cymene, β-thujene, *trans*-β-farnesene, 1(5),11-guaiadiene, sabinene, 4-butyl-1,2-dimethoxybenzene, isogermacrene D, α-amorphene, decanal and veratraldehyde; constituents ($n=42$) between <0.1% and ≥0.02%: *m*-cymen-8-ol, *cis*-*p*-2-menthen-1-ol, 4-epi-cubebol, nojigiku acetate, 4,6,10,10-tetramethyl-5-oxatricyclo[4.4.0.0(1,4)]dec-2-en-7-ol, 2,6-dimethylhept-5-enal, terpinolene, humulene oxide II, *trans*-verbenol, 2-isopropylidene-5-methylhex-4-enal, γ-terpinene, 6,7-dihydrogeraniol, *cis*-piperitol, neryl acetate, *(Z)*-sesquisabinene hydrate, neointermedeol, (+)-cedrol, [2-methyl-2-(4-methyl-3-pentenyl)cyclopropyl]methanol, *d,l*-isobornyl formate, germacra-4(15),5,10(14)-trien-1a-ol, (*R*)-5-methyl-2-(1-methylvinyl)hex-4-enal, *trans*-pinocarvyl acetate, camphenilone, δ-cadinene, cedran-diol, (8*S*,14)-, neomenthoglycol, sesquisabinene, *cis*-muurola-4(15),5-diene, *p*-mentha-1,8-dien-7-ol, (*Z*)-9,17-octadecadienal, 6-methylhept-5-en-2-one, 6-hepten-2-ol, 2,6-dimethyl-, *cis*-β-terpineol, cubenol, *cis*-carveol, 2,4-dimethoxybenzyl alcohol, citronellyl 4-methyl valerate, trans-carveol, 2,4-thujadiene, cubebol, citronellic acid and 6-camphenol.

TABLE 2 Constituents of the essential oil from the leaves (fresh or partly dried) *Cymbopogon nardus* (L.) Rendle, accounting for > 0.5% of the composition (based on the analysis of four batches by GC–MS) and not included in the specifications.

Constituent			% GC area	
EU register name	**CAS no**	**FLAVIS no**	**Mean**	**Range**
d,l-Borneol	507-70-0	02.016	6.77	6.65–6.88
Camphene	79-92-5	01.009	6.52	5.60–7.46
α-Farnesene	502-61-4	01.040	4.75	3.37–5.33
Geranyl acetate	105-87-3	09.011	3.62	3.14–4.97
β-Caryophyllene	87-44-5	01.007	2.40	1.91–2.58
Geranyl butyrate	106-29-6	09.048	2.39	2.22–2.64
α-Pinene (pin-2(3)-ene)	80-56-8	01.004	1.93	1.57–2.27
Orthodene	4889-83-2	–	1.71	1.47–1.85
α-Terpineol	98-55-5	02.014	1.53	1.48–1.57
δ-Amorphene	189165-79-5	–	1.52	1.04–1.77
Hedycaryol	21657-90-9	–	1.41	1.35–1.52
(*l*)-*cis*-Carane	2778-68-9	–	1.30	1.24–1.37
β-Copaene	18252-44-3	–	1.30	0.83–1.46
β-Eudesmol	473-15-4	–	1.18	1.10–1.30
trans-Isoelemicin	5273-85-8	–	1.05	0.81–1.15
β-Elemene	33880-83-0	–	1.03	0.78–1.15
Tricyclene	508-32-7	01.060	1.02	0.80–1.25
(*Z*)-Methyl isoeugenol	6380-24-1	–	0.93	0.82–0.98
Phthalic acid, diethyl ester	84-66-2	–	0.77	0.77–0.77
4-Terpinenol	562-74-3	02.072	0.73	0.69–0.76
Citronellyl butyrate	141-16-2	09.049	0.72	0.63–0.80
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	0.70	0.61–0.74
β-Ocimene	13,877–91-3	01.018	0.66	0.60–0.72
Cyclohexene, 4-methyl-3-(1-methylethylidene)-	99,805–90-0	–	0.61	0.44–0.74
γ-Muurolene	30,021–74-0	–	0.59	0.42–0.68
Methyleugenol[a]	93-15-2	04.012	0.57	0.41–1.00
d,l-Bornyl acetate	76–49-3	09.017	0.55	0.52–0.60
α-Bergamotene	17,699–05-7	–	0.54	0.47–0.67
Total			48.17	47.00–48.76[b]

Note: The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%.

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

[a]Substance which shall not be added as such to food (Annex III), maximum level in food is set by Regulation (EC) No 1334/2008, including dairy products (20 mg/kg), meat products (15 mg/kg), fish products (10 mg/kg), soups and sauces (60 mg/kg), ready-to eat savouries (20 mg/kg) and non-alcoholic beverages (1 mg/kg).

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

The applicant performed a literature search (see Section 3.3) for the chemical composition of *C. nardus* and its preparations to identify the presence of any recognised substances of concern.[21] The presence of methyleugenol (51–204 mg/kg) in citronella oil from *C. nardus* (L.) Rendle was reported in the EFSA compendium of botanicals.[22]

An analysis of the four batches of citronella oil under assessment confirmed the presence of methyleugenol in all batches (range 0.41%–1.00%).

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

3.2.2 | Impurities

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

[21]Technical dossier/Supplementary information June 2023/Literature search_citronella_oil.

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

Since citronella oil from *C. nardus* is produced by steam distillation, the likelihood of any measurable carry-over of all the above-mentioned elements is considered low, except for mercury.

3.2.3 | Shelf-life

The typical shelf-life of citronella oil from *C. nardus* is stated to be at least 12 months, when stored in tightly closed containers under standard conditions (in a cool, dry place protected from light).[23] However, no data supporting this statement were provided.

3.2.4 | Conditions of use

Citronella oil from *C. nardus* is intended to be added to feed and water for drinking for all animal species without a withdrawal period. Maximum use levels in complete feed were proposed for the animal species and categories listed in Table 3. No use level has been proposed by the applicant for use in water for drinking.

TABLE 3 Conditions of use for the essential oil from the fresh or partly dried leaves of *Cymbopogon nardus* (L.) Rendle: Maximum proposed use levels in complete feed for the intended target animal species and categories.

Animal category	Maximum proposed use level (mg/kg complete feed)
Long-living and reproductive animals	
Laying hens	3.5
Sows lactating	6.0
Dairy cows	6.0
Sheep/goats	9.5
Horses	9.5
Rabbits	3.5
Dogs	10
Cats	2.0
Species for fattening	
Chickens for fattening	30
Turkeys for fattening	30
Piglets	20
Pigs for fattening	20
Veal calves (milk replacer)	20
Cattle for fattening	20
Sheep/goats (for meat production)	20
Horses (for meat production)	20
Rabbits (for meat production)	20
Fish (salmon)	30

3.3 | Safety

The assessment of safety of citronella oil from *C. nardus* is based on the maximum use levels proposed by the applicant in complete feed for the species listed above (see Table 3).

No studies to support the safety for target animals, consumers and users were performed with the additive under assessment. The applicant carried out a structured database search to identify data related to the chemical composition and the safety of preparations obtained from *C. nardus*.[24] Four cumulative databases (LIVIVO, NCBI, OVID and ToxInfo), 13 single databases including PubMed and Web of Science and 12 publishers' search facilities including Elsevier, Ingenta, Springer

[23]Technical dossier/Section II.

[24]Technical dossier/Supplementary information June 2023/Literature search_citronella_oil.

and Wiley were used. The literature search (no time limits) was conducted in December 2022. The keywords used covered different aspects of safety and the inclusion and exclusion criteria were provided by the applicant.

Many of the individual components of the essential oil have been already assessed as chemically defined flavourings for use in feed and food by the FEEDAP Panel, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC), the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and the EFSA Panel on Food Additives and Flavourings (FAF) and/or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The flavouring compounds currently authorised for feed[25] and/or food[26] use, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000,[27] and the corresponding EFSA opinion are listed in Table 4.

TABLE 4 Flavouring compounds already assessed by EFSA 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
01	Straight-chain primary aliphatic alcohols/ aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes	Decanal	05.010	2013
03	α,β-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters	Geraniol	02.012	2016a
		3,7,11-Trimethyldodeca-2,6,10-trien-1-ol (farnesol)	02.029	
		Neral	05.170	
		trans-3,7-Dimethylocta-2,6-dienal (geranial)	05.188	
		Geranyl acetate	09.011	
		Geranyl butyrate	09.048	
		Neryl acetate	09.213	
		Geranyl hexanoate	09.067	2009, CEF
04	Non-conjugated and accumulated unsaturated straight-chain and branched-chain aliphatic primary alcohols, aldehydes, acids, acetals and esters	Citronellol	02.011	2016b
		Citronellal	05.021	
		2,6-Dimethylhept-5-enal	05.074	
		Citronellic acid	08.036	
		Citronellyl butyrate	09.049	
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	6-Methyhept-5-en-2-one	07.015	2015a, 2021b
		Isopulegol	02.067	2020
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012b
		α-Terpineol	02.014	
		4-Terpinenol	02.072	
		Linalyl formate	09.080	
		(+)-Cedrol[(a)]	02.120	2011a, CEF 2015a, CEF
07	Primary alicyclic saturated and unsaturated alcohols/aldehydes/acids/acetals/esters with esters containing alicyclic alcohols	*p*-Mentha-1,8-dien-7-ol	02.060	2017, CEF

[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 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.

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

TABLE 4 (Continued)

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA opinion,* year
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	*d,l*-Borneol	02.016	2016c
		d,l-Isoborneol	02.059	
		d,l-Bornyl acetate	09.017	
		Sabinene hydrate[a,b]	02.085	JECFA
		p-Menth-1-en-3-one[a]	07.175	2011b, CEF
		d,l-Isobornyl formate[a]	09.176	2012, CEF
18	Allylhydroxybenzenes	Eugenol	04.003	2011
23	Benzyl alcohols/aldehydes/ acids/esters/acetals	Veratraldehyde	05.017	2012c
26	Aromatic ethers including anisole derivatives	1,2-Dimethoxy-4-(prop-1-enyl) benzene[c] (methyl isoeugenol)	04.013	2012d
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	Limonene[a,d]	01.001	2008, EFSA AFC
		Terpinolene	01.005	2015b
		γ-Terpinene	01.020	
		Pin-2(10)-ene (β-pinene)	01.003	2016d
		Pin-2(3)-ene (α-pinene)	01.004	
		β-Caryophyllene	01.007	
		Camphene	01.009	
		3,7-Dimethyl-1,3,6-octatriene (β-ocimene)[e]	01.018	
		δ-Cadinene[a,f]	01.021	2011c, CEF
		1(5),11-Guaiadiene[a,f]	01.023	
		1,1,7-trimethyltricyclo [2.2.1.0.(2.6)] heptane (tricyclene)[a,f]	01.060	
		4(10)-Thujene (sabinene)[a]	01.059	2015b, CEF
		β-Bourbonene[a]	01.024	2015c, CEF
		α-Farnesene[a]	01.040	
32	Epoxides	β-Caryophyllene epoxide[a]	16.043	2014, CEF

Abbreviations: FLAVIS No, EU Flavour Information System number.

*FEEDAP opinion unless otherwise indicated.

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

[b]EFSA evaluated sabinene hydrate [02.085] as a mixture of *cis*- and *trans*-sabinene hydrate.

[c]EFSA evaluated 1,2-dimethoxy-4-(prop-1-enyl)benzene [04.013] or methyl isoeugenol, a mixture of (*Z*)- and (*E*)-isomers (EFSA FEEDAP Panel, 2012d).

[d]JECFA and EFSA evaluated d-limonene [01.045] (EFSA, 2008). d-Limonene [01.045] and l-limonene [01.046] were also evaluated for use in feed (EFSA FEEDAP Panel, 2015b).

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

[f]Evaluated applying the 'Procedure' described in the Guidance on the data required for the risk assessment of flavourings to be used in or on food (EFSA CEF Panel, 2010). No longer authorised for use as flavours in food, as the additional toxicity data requested (EFSA CEF Panel, 2011c) were not submitted and the CEF Panel was unable to complete its assessment.

As shown in Table 4, a number of components of citronella oil, accounting for about 81% of the GC peak areas, have been previously assessed and considered safe for use as flavourings, and are currently authorised for use in food[28] without limitations and for use in feed[29] at individual use levels higher than those resulting from the intended use of the essential oil under assessment in feed.

Three compounds listed in Table 4, δ-cadinene [01.021], 1(5),11-guaiadiene [01.023] and tricyclene [01.060], have been evaluated in Flavouring Group Evaluation 25, Revision 2 (EFSA CEF Panel, 2011c) by applying the procedure described in the Guidance on the data required for the risk assessment of flavourings to be used in or on foods (EFSA CEF Panel, 2010). For these compounds, for which there is no concern for genotoxicity, EFSA requested additional subchronic toxicity data (EFSA CEF Panel, 2011c). In the absence of such toxicological data, the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015b). As a result, these compounds are no longer authorised for use as flavours in food. For these compounds, in the absence of toxicity data, the FEEDAP Panel applies the threshold of toxicological concern (TTC) approach or

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

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

read-across from structurally related substances, as recommended in the Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019a).

Sixty compounds have not been previously assessed for use as flavourings. The FEEDAP Panel notes that 45 of them[30] accounting together for 16.2% of the GC area are aliphatic mono- or sesquiterpenes structurally related to flavourings already assessed in CGs 3, 5, 6, 8, 10, 26, 31 and 32 for which a similar metabolic and toxicological profile is expected. Because of their lipophilic nature, they are expected to be rapidly absorbed from the gastro-intestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted (EFSA CEF Panel, 2014; EFSA FEEDAP Panel, 2012b, 2012d, 2015b, 2016b, 2016c, 2016d).

The oil under assessment contains methyleugenol (0.41%–1.00%), which is genotoxic and carcinogenic in rodents. The following sections focus on methyleugenol and 15 compounds[31] not structurally related to flavourings previously assessed, based on the evidence provided by the applicant in the form of literature searches and Quantitative Structure–Activity Relationship (QSAR) analysis. For the absorption, distribution, metabolism and excretion (ADME) and the toxicology of methyleugenol, reference is made to the safety evaluation made by the FEEDAP Panel in the opinion on laurel leaf oil (EFSA FEEDAP Panel, 2023b).

3.3.1 | Toxicology

3.3.1.1 | *Genotoxicity and carcinogenicity*

For fully defined mixtures, the EFSA Scientific Committee (EFSA SC) recommends applying a component-based approach, i.e. assessing all components individually for their genotoxic potential using all available information, including read-across and QSAR considerations about their genotoxic potential (EFSA Scientific Committee, 2019). Therefore, the potential genotoxicity of identified constituents is first considered. Then, in vitro genotoxicity studies performed with citronella oils similar to the additive under assessment are considered, if deemed relevant.

Fifteen compounds, namely 2-isopropylidene-5-methylhex-4-enal, (*R*)-5-methyl-2-(1-methylvinyl)hex-4-enal, (*Z*)-9,17-octadecadienal, citronellyl 4-methyl valerate, *cis-p*-2-menthen-1-ol, *m*-cymen-8-ol, [2-methyl-2-(4-methyl-3-pentenyl)cyclopropyl] methanol, 6-camphenol, nojigiku acetate, germacra-4(15),5,10(14)- trien-1a-ol, (8S,14)-cedran-diol, 2,5-bornanediol, 4,6,10,10-tetramethyl-5-oxatricyclo[4.4.0.0(1,4)]dec-2-en-7-ol, 2,4-dimethoxybenzyl alcohol and phthalic acid diethyl ester, were screened for their genotoxic potential with the Organisation for Economic Co-operation and Development (OECD) QSAR Toolbox.[32] No alerts were identified for in vitro mutagenicity, genotoxic and non-genotoxic carcinogenicity, or other toxicity endpoints for [2-methyl-2-(4-methyl-3-pentenyl)cyclopropyl]methanol, 6-camphenol, 2,5-bornanediol and (8S, 14)-cedran-diol. For the other compounds, structural alerts were due to the presence of (i) an aldehyde group for 2-isopropylidene-5-methylhex-4-enal, (*R*)-5-methyl-2-(1-methylvinyl)hex-4-enal and (*Z*)-9,17-octadecadienal; (ii) an ester group for citronellyl 4-methyl valerate, nojigiku acetate and diethyl phthalate; (iii) a vinyl/allyl alcohol group for *cis-p*-2-menthen-1-ol and germacra-4(15),5,10(14)-trien-1a-ol; (iv) a vinyl/allyl ether group and 'H acceptor-path 3-H acceptor' pattern for 4,6,10,10-tetramethyl-5-oxatricyclo[4.4.0.0(1,4)]dec-2-en-7-ol; (v) an arene/benzyl alcohol group for *m*-cymen-8-ol and (vi) a benzyl alcohol/1,3-dialkoxybenzene group for 2,4-dimethoxybenzyl alcohol. In all cases, predictions of Ames mutagenicity were made by 'read-across' analyses of data available for similar substances to the target compounds (i.e. analogues obtained by categorisation). Categories were defined using general mechanistic and endpoint profilers as well as empirical profilers. Subcategorisation was performed in order to exclude analogues less similar to the target compounds. For all compounds mutagenicity read-across-based predictions were found negative.[33] On this basis, the alerts raised were discounted.

Methyleugenol

All batches of citronella oil from *C. nardus* contained methyleugenol (0.57% on average, range: 0.41%–1.00%), a compound with experimentally proven genotoxicity and carcinogenicity in rodents (EMA, 2005; IARC, 2018; NTP, 2000).

For methyleugenol, the FEEDAP Panel identified a reference point for neoplastic endpoints derived from a carcinogenicity study in rat (NTP, 2000) by applying the benchmark dose (BMD) approach with model averaging. Dose–response modelling using hepatocellular carcinomas in male rats as a response yielded a BMD lower confidence limit for a benchmark

[30]6,7-Dihydrogeraniol (CG 3); neoisoisopulegol (CG 5); T-muurolol, β-eudesmol, 4-epi-cubebol, T-cadinol, 6-hepten-2-ol, 2,6-dimethyl-, *cis*-β-terpineol, camphene hydrate, (*Z*)-sesquisabinene hydrate, cubebol, hedycaryol, epi-γ-eudesmol, neointermedeol, cubenol (CG 6); camphenilone, *cis*-carveol, *trans*-verbenol, isocarveol, *cis*-piperitol, *trans*-carveol, *trans*-pinocarvyl acetate (CG 8); neomenthoglycol (CG 10); *trans*-isoelemicin, *(Z)*-methyl isoeugenol, 4-butyl-1,2-dimethoxybenzene (CG 26); *trans*-β-farnesene, β-elemene, cyclohexene, 4-methyl-3-(1-methylethylidene)-, *o*-cymene, γ-muurolene, α-amorphene, β-copaene, 2,4-thujadiene, 4-carene, β-thujene, orthodene, (−)-*cis*-carane, α-bergamotene, sesquisabinene, *cis*-muurola-4(15),5-diene, γ-amorphene, δ-amorphene, isogermacrene D (CG 31); humulene oxide II (CG 32).

[31]2-Isopropylidene-5-methylhex-4-enal, (*R*)-5-methyl-2-(1-methylvinyl)hex-4-enal, (*Z*)-9,17-octadecadienal, citronellyl 4-methyl valerate, *cis-p*-2-menthen-1-ol, *m*-cymen-8-ol, [2-methyl-2-(4-methyl-3-pentenyl)cyclopropyl] methanol, 6-camphenol, nojigiku acetate, germacra-4(15),5,10(14)- trien-1a-ol, (8S,14)-cedran-diol, 2,5-bornanediol, 4,6,10,10-tetramethyl-5-oxatricyclo[4.4.0.0(1,4)]dec-2-en-7-ol, 2,4-dimethoxybenzyl alcohol and phthalic acid diethyl ester.

[32]Technical dossier/Supplementary information June 2023/Annex_VII_Sin_reply_citronella_oil_QSAR.

[33]For 9,17-octadecadienal, (Z)- and 4,6,10,10-tetramethyl-5-oxatricyclo[4.4.0.0(1,4)]dec-2-en-7-ol some predictions could not be made as there were no chemicals remaining in the category after subcategorisation.

response of 10% ($BMDL_{10}$) of 22.2 mg/kg bw per day (Suparmi et al., 2019). This $BMDL_{10}$ value was selected as reference point for the assessment group of *p*-allylalkoxybenzenes irrespective of their relative potency (EFSA FEEDAP Panel, 2022).

The FEEDAP Panel also identified a no observed adverse effect level (NOAEL) of 10 mg/kg bw per day for non-neoplastic lesions (changes in organ weight[34] and function, including effects on liver[35] and the glandular stomach[36]) from a 90-day study in mice with methyleugenol (NTP, 2000).

Genotoxicity studies with citronella oil

The literature search provided by the applicant[37] (see Section 3.3) identified several publications on the genotoxicity of citronella oil. The genotoxicity of citronella oil was reviewed in the FEMA GRAS assessment of natural flavour complexes (Rosol et al., 2023). The FEEDAP Panel noted that the assessment reporting negative results was based on unpublished reports, which were not made available by the applicant. Therefore, this article was not further considered for the assessment of genotoxicity of citronella oil. Two articles by Sinha et al. (2011, 2014) were not further considered in the safety assessment of citronella oil due to limitations identified by the FEEDAP Panel in the description of the test item and lack of biological relevance of the results. The oil contains several cytotoxic compounds which restrict in vitro testing at higher concentrations.

3.3.2 | Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals made with the essential oil under application were not submitted.

In the absence of these data, the approach to the safety assessment of a mixture whose individual components are known is based on the safety assessment of each individual component (component-based approach). This approach requires that the mixture is sufficiently characterised and that the individual components can be grouped into assessment groups, based on structural and metabolic similarity. The combined toxicity can be predicted using the dose addition assumption within an assessment group, taking into account the relative toxic potency of each component (EFSA Scientific Committee, 2019a).

As the additive under assessment is a fully defined mixture (the identified components represent 100% of the % GC area, see Section 3.2.1), the FEEDAP Panel applied a component-based approach to assess the safety for target species of the essential oil of citronella from *C. nardus*. Methyleugenol, a substance for which a concern for genotoxicity has been identified, is assessed separately.

Components other than methyleugenol

Based on considerations related to structural and metabolic similarities, the components were allocated to 13 assessment groups, corresponding to chemical groups (CGs) 1, 3, 4, 5, 6, 7, 8, 9, 10, 23, 36, 31 and 32, as defined in Annex I of Regulation (EC) No 1565/2000.[38] For chemical group 31 ('aliphatic and aromatic hydrocarbons'), sub-assessment groups as defined in Flavouring Group Evaluation 25 (FGE.25) and FGE.78 were established (EFSA CEF Panel, 2015b, 2015c). The allocation of the components to the (sub-)assessment groups is shown in Table 5 and in the corresponding footnote.

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

For hazard characterisation, each component of an assessment group was first assigned to the structural class according to Cramer classification (Cramer et al., 1978). For some components in the assessment groups, toxicological data were available to derive no observed adverse effect level (NOAEL) values. 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 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.[39]

[34]Increases in absolute liver weights of rats (at doses of 100 mg/kg of higher in males and at doses of 300 mg/kg of higher in females) and mice (at 30, 100 and 300 mg/kg in males and at 300 mg/kg in females) and the increase in testis weight of rats administered 1000 mg/kg.

[35]Cytologic alteration, cytomegaly, Kupffer cell pigmentation, bile duct hyperplasia and foci of cellular alteration.

[36]Incidences of atrophy and chronic inflammation of the mucosa of the glandular stomach were significantly increased in rats administered 300 or 1000 mg/kg; the incidences of lesions of the glandular stomach were increased in one or more groups administered 30 mg/kg or greater.

[37]Technical dossier/Supplementary information June 2023/Literature search citronella oil.

[38]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.

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

Toxicological data of subchronic studies, from which NOAEL values could be derived, were available for several compounds in CG 1 (EFSA FEEDAP Panel, 2013), for the representative compound citral [05.020] in CG 3 (EFSA FEEDAP Panel, 2016a), for citronellol [02.011] and 2,6-dimethylhept-5-enal [05.074] in CG 4 (EFSA FEEDAP Panel, 2016b), 6-methylhept-5-en-2-one [07.015] in CG 5 (EFSA FEEDAP Panel, 2021b), terpineol [02.230][40] and linalool [02.013] in CG 6 (EFSA FEEDAP Panel, 2021b), *d,l*-isobornyl acetate [09.218] in CG 8 (EFSA FEEDAP Panel, 2016c), methyl isoeugenol [04.013] in CG 26 (EFSA FEEDAP Panel, 2012d), and for the representative compounds for sub-assessment groups of CG 31, myrcene [01.008], d-limonene [01.045] and β-caryophyllene (EFSA FEEDAP Panel, 2015b, 2016d), and β-caryophyllene epoxide [16.043] for CG 32 (EFSA CEF Panel, 2014). For *d*-carvone [01.146], not present in the essential oil but structurally related to some components, the applicant referred to a $BMDL_{10}$ of 60 mg/kg bw per day (EFSA FEEDAP Panel, 2016c; EFSA Scientific Committee, 2014).

For CG 1, a group NOAEL of 120 mg/kg was derived from the toxicological data available and was extrapolated to decanal [05.010]. The NOAEL of 345 mg/kg bw per day for citral [05.020] was used as a group NOAEL for compounds belonging to CG 3, i.e. neral [05.170], geraniol [02.012], geranial [05.188], geranyl acetate [09.011], geranyl butyrate [09.048], geranyl hexanoate [09.067], neryl acetate [09.213] and 6,7-dihydrogeraniol. Similarly, the NOAEL of 50 mg/kg bw per day for citronellol [02.011] was used as a group NOAEL and applied to the citronellyl derivatives in CG 4, i.e. citronellal [05.021], citronellic acid [08.036], citronellyl butyrate [09.049] and citronellyl 4-methyl valerate. In CG 5, the NOAEL of 38 mg/kg bw per day for isopulegol [02.067] (EFSA FEEDAP Panel, 2020) was applied using read-across to neoisoisopulegol.

For the subgroup of terpinyl derivatives in CG 6, i.e. α-terpineol [02.014], 4-terpinenol [02.072] and *cis*-β-terpineol, the reference point was selected based on the NOAEL of 250 mg/kg bw per day available for terpineol [02.230] and *d*-limonene [01.045]. The NOAEL of 250 mg/kg bw per day was also extrapolated to hedycaryol, β-eudesmol, T-cadinol, T-muurolol, epi-γ-eudesmol, *cis*-*p*-menthen-1-ol, 4-epi-cubebol, neointermedeol, (+)-cedrol [02.120], cubenol and cubebol. The NOAEL of 117 mg/kg bw per day for linalool [02.013] was extrapolated to linalyl formate [09.080].

In CG 8, the NOAEL of 15 mg/kg bw per day of *d,l*-isobornyl acetate [09.218] was extrapolated to *d,l*-borneol [02.016], *d,l*-isoborneol [02.059], *d,l*-isobornyl formate [09.176] and *d,l*-bornyl acetate [09.017]. The $BMDL_{10}$ of 60 mg/kg bw per day for *d*-carvone [07.146] was extrapolated to *cis*-carveol, isocarveol and *trans*-carveol.

The NOAEL of 400 mg/kg bw per day for vanillin [05.018] was extrapolated to veratraldehyde [05.017] in CG 23. In CG 26, the NOAEL of 50 mg/kg bw per day for methyl isoeugenol [04.013] was applied to the isomers (*E*)- and (*Z*)-methyl isoeugenol and to *trans*-isoelemicin.

The NOAELs of 44, 250 and 222 mg/kg bw per day for the representative compounds in CG 31, myrcene [01.008], d-limonene [01.045] and β-caryophyllene [01.007] were applied using read-across to the compounds within sub-assessment group II (β-ocimene [01.018], α-farnesene [01.040], *trans*-β-farnesene), sub-assessment group III (limonene [01.001], γ-terpinene [01.020], terpinolene [01.005] and β-elemene), and sub-assessment group V,[41] respectively (EFSA CEF Panel, 2015b, 2015c). The NOAEL for β-caryophyllene was also extrapolated to camphene hydrate, sabinene hydrate [02.085] and (*Z*)-sesquisabinene hydrate in CG 6 and to nojigiku acetate, *trans*-verbenol, *trans*-pinocarvyl acetate, camphenilone and 6-camphenol.

The NOAEL of 109 mg/kg bw per day for β-caryophyllene epoxide [16.043] was used for humulene oxide II in CG 32.

For the remaining compounds,[42] toxicity studies performed with the compounds under assessment and NOAEL values derived from toxicity studies were not available and read-across was not possible. Therefore, the threshold of toxicological concern (TTC) approach was applied (EFSA FEEDAP Panel, 2017b; EFSA Scientific Committee, 2019).

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

For risk characterisation, the margin of exposure (MOE) was calculated for each component as the ratio between the reference point and the exposure. For each assessment group, the combined (total) margin of exposure (MOET) was calculated as the reciprocal of the sum of the reciprocals of the MOE of the individual substances (EFSA Scientific Committee, 2019). A MOET > 100 allowed for interspecies- and intra-individual variability (as in the default 10 × 10 uncertainty factor). The compounds resulting individually in an MOE > 50,000 were not further considered in the assessment group as their contribution to the MOE(T) is negligible. They are listed in the footnote.[43]

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

[41]Compounds in sub-assessment group V in which read-across from β-caryophyllene [01.007] was applied: tricyclene; α-pinene, camphene, β-bourbonene, γ-muurolene, α-amorphene, δ-cadinene, β-pinene, β-copaene, sabinene, 4-carene; β-thujene, orthodene, (−)-*cis*-carane, α-bergamotene, sesquisabinene, *cis*-muurola-4(15),5-diene γ-amorphene; 1(5),11-guaiadiene and δ-amorphene.

[42]CC I (3 mg/kg bw per day): 2-isopropylidene-5-methylhex-4-enal, (*R*)-5-methyl-2-(1-methylvinyl)hex-4-enal (CG 3); (*Z*)-9,17-octadecadienal, (CG 4); *m*-cymen-8-ol, 6-hepten-2-ol, 2,6-dimethyl (CG 6); *p*-mentha-1,8-dien-7-ol (CG 7); *p*-menth-1-en-3-one, germacra-4(15),5,10(14)-trien-1a-ol (CG 8); 2,5-bornanediol, neomenthoglycol (CG 10); 2,4-dimethoxybenzyl alcohol (CG 23), 4-butyl-1,2-dimethoxybenzene, *trans*-isoelemicin (CG 26); cyclohexene, 4-methyl-3-(1-methylethylidene)- (CG 31, II); *o*-cymene (CG 31, IVa); isogermacrene D (CG 31, VI) and phthalic acid, diethyl ester. CC II (0.91 mg/kg bw per day): 2-methyl-2-(4-methyl-3-pentenyl)cyclopropyl]methanol (CG 7). CC III (0.15 mg/kg bw per day): (8*S*,14)-cedran-diol (CG 9); 4,6,10,10-tetramethyl-5-oxatricyclo[4.4.0.0(1,4)]dec-2-en-7-ol (CG 10); 2,4-thujadiene (CG 31, V).

[43]Geranyl hexanoate, 6,7-dihydrogeraniol, neryl acetate (CG 3); *cis*-*p*-menthene-1-ol, 4-epi-cubebol, *cis*-β-terpineol, cubebol, *(Z)*-sesquisabinene hydrate, neointermedeol, (+)-cedrol, cubenol (CG 6); nojigiku acetate, *trans*-verbenol, *trans*-pinocarvyl acetate, camphenilone, *cis*-piperitol, *d,l*-isobornyl formate, 6-camphenol, *cis*-carveol, *trans*-carveol (CG 8); veratraldehyde (CG 23); γ-terpinene, terpinolene (CG 31,III); 1(5),11-guaiadiene, β-thujene, sabinene, α-amorphene, sesquisabinene, δ-cadinene, *cis*-muurola-4(15),5-diene, (CG31,V), humulene oxide II (CG 32).

The approach to the safety assessment of citronella oil for the target species is summarised in Table 5. The calculations were done for chickens for fattening, the species with the highest ratio of feed intake/body weight and represent the worst-case scenario at the use level of 30 mg/kg complete feed.

TABLE 5 Compositional data, intake values (calculated for chickens for fattening at 30 mg/kg complete feed), reference points, margin of exposure (MOE) for the individual components of citronella oil from C. nardus classified according to assessment groups and combined margin of exposure (MOET) for each assessment group.

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS no**	**Highest conc. in the oil**	**Highest feed conc.**	**Intake[a]**	**Cramer class[b]**	**NOAEL[c]**	**MOE**	**MOET**
Constituent	**–**	**%**	**mg/kg**	**mg/kg bw per day**	**–**	**mg/kg bw per day**	**–**	**–**
CG 1								
Decanal	05.010	0.11	0.033	0.00296	(I)	120	40,506	
CG 3								
Geraniol	02.012	18.33	5.499	0.4937	(I)	345	699	
Geranyl acetate	09.011	4.97	1.491	0.1339	(I)	345	2577	
Geranyl butyrate	09.048	2.64	0.792	0.0711	(I)	345	4852	
Geranial	05.188	0.68	0.204	0.0183	(I)	345	18,838	
Neral	05.170	0.28	0.084	0.0075	(I)	345	45,750	
2-Isopropylidene-5-methylhex-4-enal	–	0.06	0.018	0.0016	I	*3*	1857	
(*R*)-5-Methyl-2-(1-methylvinyl)hex-4-enal		0.06	0.018	0.0016	I	*3*	1857	
MOET CG 3								315
CG 4								
Citronellal	05.021	5.12	1.536	0.1379	(I)	50	363	
Citronellol	02.011	4.57	1.371	0.1231	(I)	**50**	406	
Citronellyl butyrate	09.049	0.80	0.240	0.0215	(I)	50	2321	
2,6-Dimethylhept-5-enal	05.074	0.08	0.024	0.0022	(I)	**37**	17,173	
Citronellic acid	08.036	0.08	0.024	0.0022	(I)	50	23,207	
Citronellyl 4-methyl valerate	–	0.04	0.012	0.0011	I	50	46,414	
(*Z*)-9,17-Octadecadienal*	–	0.04	0.012	0.0011	I	*3*	2785	
MOET CG 4								163
CG 5								
Neoisoisopulegol	07.189	0.14	0.042	0.0038	(I)	38	10,078	
6-Methylhept-5-en-2-one*	07.015	0.04	0.012	0.0011	(II)	**50**	46,414	
MOET CG 5								8280
CG 6								
α-Terpineol	02.014	1.57	0.471	0.0423	(I)	250	5913	
Hedycaryol	–	1.52	0.456	0.0409	(I)	250	6107	
β-Eudesmol	–	1.30	0.390	0.0350	(I)	250	7141	
4-Terpinenol	02.072	0.76	0.228	0.0205	(I)	250	12,214	
Linalool	02.013	0.61	0.183	0.0164	(I)	**117**	7122	
Camphene hydrate	–	0.35	0.105	0.0094	(I)	222	23,552	
T-Cadinol	–	0.29	0.087	0.0078	(I)	250	32,009	
Sabinene hydrate	02.085	0.26	0.078	0.0070	(I)	222	31,704	
T-Muurolol	–	0.25	0.075	0.0067	(I)	250	37,131	
epi-γ-Eudesmol	–	0.25	0.075	0.0067	(I)	250	37,131	
Linalyl formate	09.080	0.21	0.063	0.0057	(I)	117	20,687	
m-Cymen-8-ol	–	0.14	0.042	0.0038	I	*3*	796	

(Continues)

TABLE 5 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS no**	**Highest conc. in the oil**	**Highest feed conc.**	**Intake[a]**	**Cramer class[b]**	**NOAEL[c]**	**MOE**	**MOET**
Constituent	**–**	**%**	**mg/kg**	**mg/kg bw per day**	**–**	**mg/kg bw per day**	**–**	**–**
6-Hepten-2-ol, 2,6-dimethyl-	–	0.05	0.015	0.0013	I	*3*	2228	
MOET CG 6								383
CG 7								
p-Mentha-1,8-dien-7-ol	02.060	0.05	0.015	0.0013	I	*3*	2228	
[2-Methyl-2-(4-methyl-3-pentenyl)cyclopropyl] methanol*	–	0.05	0.015	0.0013	II	*0.91*	676	
MOET CG 7								519
CG 8								
d,l-Borneol	02.016	6.88	2.064	0.1853	(I)	15	81	
d,l-Bornyl acetate	09.017	0.60	0.180	0.0162	(I)	15	928	
p-Menth-1-en-3-one	07.175	0.27	0.081	0.0073	I	*3*	413	
Isocarveol	–	0.24	0.072	0.0065	(I)	60	9283	
d,l-Isoborneol	02.059	0.16	0.048	0.0043	(I)	15	3481	
Germacra-4(15),5,10(14)-trien-1a-ol	–	0.06	0.018	0.0016	I	*3*	1857	
MOET CG 8								59
CG 9								
Cedran-diol, (8S,14)-	–	0.05	0.015	0.0013	III	*0.15*	111	
CG 10								
2,5-Bornanediol	–	0.29	0.087	0.0078	I	*3*	384	
Neomenthoglycol	–	0.05	0.015	0.0013	I	*3*	2228	
4,6,10,10-Tetramethyl-5-oxatricyclo[4.4.0.0(1,4)] dec-2-en-7-ol *	–	0.07	0.021	0.0019	III	*0.15*	80	
MOET CG 10								64
CG 23								
2,4-Dimethoxybenzyl alcohol *	–	0.04	0.012	0.0011	I	*3*	2785	
CG 26								
(*E*)-Methyl isoeugenol	04.013	13.89	4.167	0.3741	(III)	**50**	134	
trans-Isoelemicin	–	1.15	0.345	0.0310	(I)	50	1614	
(*Z*)-Methyl isoeugenol	–	0.98	0.294	0.0264	(I)	50	1894	
4-Butyl-1,2-dimethoxybenzene	–	0.12	0.036	0.0032	I	*3*	928	
MOET CG 17								103
CG 31, II								
α-Farnesene	01.040	5.33	1.599	0.1435	(I)	44	307	
β-Ocimene	01.018	0.72	0.216	0.0194	(I)	44	2269	
trans-β-Farnesene	–	0.14	0.042	0.0038	(I)	44	11,670	
MOET CG 31, II								264
CG 31, III								
Limonene	01.001	7.18	2.154	0.1934	(I)	250	1293	
β-Elemene	–	1.15	0.345	0.0310	I	*3*	8072	

TABLE 5 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS no**	**Highest conc. in the oil**	**Highest feed conc.**	**Intake[a]**	**Cramer class[b]**	**NOAEL[c]**	**MOE**	**MOET**
Constituent	**–**	**%**	**mg/kg**	**mg/kg bw per day**	**–**	**mg/kg bw per day**	**–**	**–**
Cyclohexene, 4-methyl-3-(1-methylethylidene)-	–	0.74	0.222	0.0199	I	*3*	151	
MOET CG 31, III								132
CG 31, IVa								
o-Cymene	–	0.21	0.063	0.0057	I	*3*	530	
CG 31, V								
Camphene	01.009	7.46	2.238	0.2009	(I)	222	1105	
β-Caryophyllene	01.007	2.58	0.774	0.0695	(I)	**222**	3195	
α-Pinene	01.004	2.27	0.681	0.0611	(I)	222	3631	
Orthodene	–	1.85	0.555	0.0498	(I)	222	4456	
δ-Amorphene	–	1.77	0.531	0.0477	(I)	222	4657	
β-Copaene	–	1.46	0.438	0.0393	(I)	222	5646	
(*l*)-*cis*-Carane	–	1.37	0.411	0.0369	(I)	222	6017	
Tricyclene	01.060	1.25	0.375	0.0337	(I)	222	6594	
β-Pinene	01.003	0.74	0.222	0.0199	(I)	222	11,139	
γ-Muurolene	–	0.68	0.204	0.0183	(I)	222	12,122	
α-Bergamotene	–	0.67	0.201	0.0180	(I)	222	12,303	
4-Carene	–	0.23	0.069	0.0062	(I)	222	35,839	
γ-Amorphene	–	0.19	0.057	0.0051	(I)	222	43,384	
β-Bourbonene	01.024	0.18	0.054	0.0048	(I)	222	45,795	
2,4-Thujadiene *	–	0.03	0.009	0.0008	III	*0.15*	186	
MOET CG 31, V								123
CG 31, VI								
Isogermacrene D	–	0.12	0.036	0.0032	I	*3*	928	
CG 32								
β-Caryophyllene epoxide	16.043	0.44	0.132	0.0119	(III)	109	9198	
MOET CG 32								7936
Phthalate								
Phthalic acid, diethyl ester*	–	0.77	0.231	0.0207	I	*3*	145	

Abbreviations: bw, body weight; FLAVIS No, EU Flavour Information System number.

[a]Intake calculations for the individual components are based on the use level of 30 mg/kg in feed for chickens for fattening, the species with the highest ratio of feed intake/body weight. The MOE for each component is calculated as the ratio of the reference point (NOAEL) to the intake. The combined margin of exposure (MOET) is calculated for each assessment group as the reciprocal of the sum of the reciprocals of the MOE of the individual substances.

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

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

*Compound only identified in one batch of the additive; assessment made based on data from one batch.

As shown in Table 5, the lowest MOET of 59 was calculated at the proposed use levels of the additive in chickens for fattening (30 mg/kg complete feed) for CG 8. From the lowest MOET for chickens for fattening, the MOET for CG 8 compounds was calculated for the other target species considering the respective daily feed intake and conditions of use. The results are summarised in Table 6.

TABLE 6 Combined margin of exposure (MOET) for the assessment group CG 8 calculated for the different target animal categories at the proposed use level and maximum safe use level in feed calculated to ensure a MOET ≥ 100.

Animal category	Daily feed intake (g DM/kg bw)	Proposed use levels (mg/kg feed)[a]	Lowest MOET CG8	Maximum safe use level (mg/kg feed)[a]
Long-living and reproductive animals				
Laying hens	53	3.5	754	–
Sows lactating	30	6.0	777	–
Dairy cows	31	6.0	752	–
Sheep/goats	20	9.5	536	–
Horses	20	9.5	536	–
Rabbits	50	3.5	582	–
Dogs	17	10	823	–
Cats	20	2.0	3496	–
Short-living animals (species for fattening)				
Chickens for fattening	79	30	59	18
Turkeys for fattening	59	30	79	24
Piglets	44	20	159	–
Pigs for fattening	37	20	189	–
Veal calves (milk replacer)	19	20	368	–
Cattle for fattening	20	20	350	–
Sheep/goats for meat production	20	20	350	–
Horses for meat production	20	20	350	–
Rabbits for meat production	50	20	140	–
Salmonids	18	30	259	–

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

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

Table 6 shows that the MOET exceed the value of 100 for all animal categories except poultry species for fattening. For these species the maximum safe use levels in feed were calculated to ensure a MOET ≥ 100. Because glucuronidation is an important metabolic reaction to facilitate the excretion of the components of the essential oil and considering that cats have an unusually low capacity for glucuronidation (Court & Greenblatt, 1997; Lautz et al., 2021), the use of citronella oil as an additive in cat feed needs a wider margin of exposure. A MOET of 500 is considered adequate.

The maximum use levels proposed by the applicant of 2.0 mg/kg for cats, 3.5 mg/kg for laying hens and rabbits, 6 mg/kg for sows and dairy cows, 9.5 mg/kg for dairy sheep/goats and horses, 10 mg/kg for dogs, 20 mg/kg for piglets, pigs for fattening, veal calves, cattle for fattening, sheep/goats for meat production, horses for meat production, rabbits for meat production, and 30 mg/kg for salmonids are safe (without considering the presence of methyleugenol). For chickens for fattening and turkeys for fattening, the maximum safe levels in feed are 18 and 24 mg/kg complete feed, respectively. These levels are extrapolated to physiologically related minor species. For the other species not considered, the lowest value of 2.0 mg/kg complete feed is applied.

No specific proposals have been made by the applicant for the use level in water for drinking. The FEEDAP Panel considers that the use in water for drinking alone or in conjunction with use in feed should not exceed the daily amount that is considered safe when consumed via feed alone.

Methyleugenol

Methyleugenol belongs to the group of *p*-allylalkoxybenzenes and is a genotoxic carcinogen. According to the General approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic (EFSA FEEDAP Panel, 2021b), different reference points and a different magnitude of the MOE are applied for long-living and reproductive animals (including those animals reared for laying/breeding/reproduction) and for short-living animals. Short-living animals are defined as those animals raised for fattening whose lifespan under farming conditions makes it very unlikely that they develop cancer as a result of the exposure to genotoxic and/or carcinogenic substances in the diet.

For long-living and reproductive animals, a MOE with a magnitude > 10,000 when comparing estimated exposure to genotoxic and/or carcinogenic substances with a $BMDL_{10}$ from a rodent carcinogenicity study is considered indicative of low concern. The FEEDAP Panel identified the $BMDL_{10}$ of 22.2 mg/kg bw per day derived from rodent carcinogenicity studies with methyleugenol (NTP, 2000; Suparmi et al., 2019), as the reference point for the entire group of *p*-allylalkoxybenzenes (EFSA FEEDAP Panel, 2022). In the current assessment, this reference point is applied to assess the exposure of long-living and reproductive animals to methyleugenol.

For short-living animals (species for fattening), genotoxicity and carcinogenicity endpoints are not considered biologically relevant; therefore, a lower magnitude of the MOE (> 100) when comparing estimated exposure with a reference point based on non-neoplastic endpoints is considered adequate (EFSA FEEDAP Panel, 2021a). The FEEDAP Panel identified a NOAEL of 10 mg/kg bw per day for non-neoplastic lesions from a 90-day study in mice with methyleugenol (EFSA FEEDAP Panel, 2023b; NTP, 2000). In the current assessment this reference point is applied to assess the exposure of short-living and reproductive animals to methyleugenol.

Methyleugenol was detected in all batches of the oil under assessment (0.57% on average, range: 0.41%–1.00%). The highest daily intake of methyleugenol was calculated considering the maximum proposed use level of the additive in feed for the different animal categories and the highest analysed concentration on the additive (1.00%). The intake values reported in Table 7, together with the corresponding MOE for the combined intake calculated considering the relevant reference point for long-living and reproductive animals and for species for fattening.

TABLE 7 Target animal intake of methyleugenol and margin of exposure (MOE) calculated at the maximum proposed use level of citronella oil from *C. nardus* in feed with a maximum content of methyleugenol of 1.00%.

Animal category	Daily feed intake (g DM/kg bw)	Maximum safe use level (mg/kg feed)[d]	Methyleugenol intake[a] (μg/kg bw per day)	MOE[b,c]
Long-living and reproductive animals[b]				
Laying hens	53	3.5	2.1	10,532
Sows lactating	30	6.0	2.1	10,792
Dairy cows	31	6.0	2.1	10,582
Sheep/goats	20	9.5	2.2	10,282
Horses	20	9.5	2.2	10,282
Rabbits	50	3.5	2.0	11,163
Dogs	17	10	1.9	11,722
Cats	20	2.0	0.5	48,840
Short-living animals (species for fattening)[c]				
Chickens for fattening	79	18	16.2	619
Turkeys for fattening	59	24	16.0	625
Piglets	44	20	10.0	1000
Pigs for fattening	37	20	8.3	1200
Veal calves (milk replacer)	19	20	4.3	2500
Cattle for fattening	20	20	4.5	2200
Sheep/goats for meat production	20	20	4.5	2200
Horses for meat production	20	20	4.5	2200
Rabbits for meat production	50	20	11.4	880
Salmonids	18	30	6.0	1676

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

[a]The intake value of methyleugenol is calculated at the highest analysed concentration of 1%.

[b]The MOE for long-living and reproductive animals is calculated as the ratio of the reference point ($BMDL_{10}$ of 22.2 mg/kg bw per day) to the combined intake.

[c]The MOE for short living animals (species for fattening) is calculated as the ratio of the reference point (NOAEL of 10 mg/kg bw per day) to the combined intake.

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

When the estimated exposures for long-living and reproductive animals are compared to the $BMDL_{10}$ of 22.2 mg methyleugenol/kg bw per day (Suparmi et al., 2019), a MOET > 10,000 is obtained for all long-living and reproductive animals, which is indicative of low concern (Table 7).

For short-living animals (species for fattening), the magnitude of the MOE is > 100 and is of no safety concern, when comparing the exposure to the reference point of 10 mg/kg bw per day for non-neoplastic endpoints.

3.3.2.1 | *Conclusions on safety for the target species*

The FEEDAP Panel concludes that the levels of citronella oil from *C. nardus* summarised in Table 8 are considered of low concern for long-living and reproductive animals and of no concern for species for fattening.

TABLE 8 Feed concentrations of citronella oil from *C. nardus* in complete feed (mg/kg) considered of low concern for long-living and reproductive animals and of no concern for target species for fattening.

Animal category	Feed concentration of low[a]/no concern[b] (mg/kg complete feed)[c]
Long-living and reproductive animals[a]	
Laying hens and other laying/reproductive birds including animals reared for laying/reproduction and ornamental birds	3.5
Sows and other Suidae species for reproduction including animals reared for reproduction	6.0
Sheep/goats	9.5
Dairy cows and other ruminants and camelids for milk production and reproduction including animals reared for milk production/reproduction	6.0
Horses and other Equidae	9.5
Rabbits	3.5
Dogs	10
Cats	2.0
Short-living animals (species for fattening)[b]	
Turkeys for fattening	24
Chickens for fattening and other poultry for fattening	18
Piglets, pigs for fattening and other Suidae species for meat production	20
Veal calves (milk replacer)	20
Sheep/goat for meat production	20
Cattle for fattening and other ruminants for fattening and camelids at the same physiological stage	20
Horses and other Equidae for meat production	20
Rabbits for meat production	20
Salmonids and minor fin fish	30
Other species	2.0

[a]Based on a MOE > 10,000 for long-living and reproductive animals, calculated as the ratio of the reference point ($BMDL_{10}$ of 22.2 mg/kg bw per day) to the combined intake.

[b]Based on a MOE > 100 for target species for fattening, calculated as the ratio of the reference point (NOAEL of 10 mg/kg bw per day) to the combined intake.

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

The FEEDAP Panel considers that the use of the additive in water for drinking alone or in combination with the use in feed should not exceed the daily amount that is considered of low concern/no concern when consumed via feed alone.

3.3.3 | Safety for the consumer

According to Fenaroli's handbook of flavour ingredients (Burdock, 2009), citronella (*C. nardus* Rendle) and its 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 daily exposure values of 0.0009 mg/kg per day for citronella and 0.0011 mg/kg per day for citronella oil (FEMA 2308). Fenaroli's handbook reports use levels of citronella oil ranging from 3.3 to 47.6 mg/kg in several food categories. The estimated human intake from the FEMA evaluation for citronella oil is 11 μg/person per day (Rosol et al., 2023).

Many of the individual constituents of the essential oil under assessment are currently authorised as food flavourings without limitations and have been already assessed for consumer safety when used as feed additives in animal production (see Table 4, Section 3.3).

No data on residues in products of animal origin were made available for any of the constituents of the essential oil. However, the Panel recognises that the constituents of the citronella oil are expected to be extensively metabolised and excreted in the target species. Consequently, relevant residues in food products are unlikely. For methyleugenol, the available data indicate that it is absorbed, metabolised and rapidly excreted and is not expected to accumulate in animal tissues and products at the levels present in the additive (EFSA FEEDAP Panel, 2023b).

The FEEDAP Panel considers that it is unlikely that the consumption of products from animals given citronella oil from *C. nardus* at the maximum proposed use level would substantially increase human background exposure. Thus, no safety concern would be expected for the consumer from the use of citronella oil up to the maximum proposed use level in feed.

3.3.4 | Safety for the user

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

The applicant provided safety data sheets for citronella oil from *C. nardus*[44] where concerns for users have been identified.

The applicant made a literature search (see Section 3.3) aimed at retrieving studies related to the safety of citronella oil.[45] There is limited evidence from the literature that citronella oil may be a potential skin irritant and skin sensitiser (reviewed by Tisserand & Young, 2014; Kandimalla et al., 2016; Kumar et al., 2021).

The FEEDAP Panel concludes that citronella oil from *C. nardus* should be considered as irritant to skin and eyes, and as a dermal sensitiser.

When handling the essential oil, exposure of unprotected users to methyleugenol may occur. Therefore, to reduce the risk, the exposure of the users should be minimised.

3.3.5 | Safety for the environment

C. nardus is not a native species to Europe and is not commonly grown in Europe. Therefore, the safety for the environment is assessed based on the individual components of the essential oil.

The five major constituents of citronella oil from *C. nardus* (citronellal, geraniol, citronellol, limonene and (*E*)-methyl isoeugenol and additional 31 components (see Table 4)) accounting together for about 75.5% of the composition of the oil, have been evaluated by EFSA as sensory additives for animal feed. They are present at high concentrations in plants native to Europe and are expected to be extensively metabolised by the target species (EFSA FEEDAP Panel, 2016a, 2016b, 2015a). Therefore, no risk to the environment is expected for these compounds from the use of citronella oil in animal feed. Concerning the other components evaluated as feed additives, they were considered to be safe for the environment at individual use levels higher than those resulting from the use of the essential oil at the maximum safe levels in feed (see Table 4, Section 3.3).

The remaining identified constituents[46] of the essential oil, which were not evaluated for use in feed, are chemically related to compounds authorised for use as feed flavourings in CG 3, 4, 6, 8, 10, 26, 31 for which EFSA concluded that they were extensively metabolised by the target species (see Section 3.3.1) and excreted as metabolites or carbon dioxide. Therefore, no risk for the safety of the environment is foreseen from these constituents. For β-caryophyllene epoxide, the applicant provided evidence on the natural occurrence in plants native to Europe.[47]

The use of citronella oil from *C. nardus* in animal feed under the proposed conditions of use is not expected to pose a risk to the environment.

3.4 | Efficacy

Citronella oil from *C. nardus* is listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by FEMA with the reference number 2308.

Since the leaves of *C. nardus* and its essential oil 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

Citronella oil from the leaves of *C. nardus* (L.) Rendle may be produced from plants with different chemical compositions resulting in preparations of different composition. Thus, the following conclusions apply only to citronella oil which contains ≤ 1% methyleugenol (*C. nardus*).

The conclusions of the FEEDAP Panel on the concentrations in complete feed of citronella oil from *C. nardus*, which are considered of low concern for long-living and reproductive animals and of no concern for species for fattening are summarised as follows:

[44]Technical dossier/Supplementary information June 2023/ Annex_X_SIn_reply_citronella_oil_MSDS_nardus_S18. Serious eye damage/irritation (H318; category 1); skin corrosion/irritation (H315, category 2); skin sensitisation (H317, category 1) in accordance with the criteria outlined in Annex I of 1272/2008/EC (CLP/EU-GHS). Information on ingredients: Methyleugenol (< 0.1–1): Suspected of causing genetic defects (H341), Suspected of causing cancer (H351).

[45]Technical dossier/Supplementary information June 2023/literature_search_citronella_oil.

[46]Constituents structurally related to compounds authorised for use as feed flavourings: geranyl hexanoate (CG 3); citronellyl butyrate (CG 4); T-muurolol, T-cadinol, sabinene hydrate, hedycaryol, epi-γ-eudesmol, camphene hydrate, β-eudesmol (CG 6); isocarveol (CG 8); 2,5-bornanediol (CG 10); *trans*-isoelemicin, *(Z)*-methyl isoeugenol (CG 26); β-ocimene, α-farnesene (CG 31, II), cyclohexene, 4-methyl-3-(1-methylethylidene)-, β-elemene (CG 31, III); *o*-cymene (CG 31, Iva); orthodene, γ-muurolene, γ-amorphene, delta-amorphene, β-thujene, β-copaene, β-bourbonene, α-bergamotene, 4-carene, (–)-*cis*-carane (CG 31, V), phathalic acid, diethyl ester and methyleugenol.

[47]Technical dossier/Supplementary information June 2023/SIn_reply_citronella oil.

Animal category	Feed concentration of low[a]/no concern[b] (mg/kg complete feed)[c]
Long-living and reproductive animals[a]	
Laying hens and other laying/reproductive birds including animals reared for laying/reproduction and ornamental birds	3.5
Sows and other Suidae species for reproduction including animals reared for reproduction	6.0
Sheep/goat	9.5
Dairy cows and other ruminants and camelids for milk production and reproduction including animals reared for milk production/reproduction	6.0
Horses and other Equidae	9.5
Rabbits	3.5
Dogs	10
Cats	2.0
Short-living animals (species for fattening)[b]	
Turkeys for fattening	24
Chickens for fattening and other poultry for fattening	18
Piglets, pigs for fattening and other Suidae species for meat production	20
Veal calves (milk replacer)	20
Sheep/goat for meat production	20
Cattle for fattening and other ruminants for fattening and camelids at the same physiological stage	20
Horses and other Equidae for meat production	20
Rabbits for meat production	20
Salmonids and minor fin fish	30
Other species	2.0

[a]Based on a MOE > 10,000 for long-living and reproductive animals, calculated as the ratio of the reference point ($BMDL_{10}$ of 22.2 mg/kg bw per day) to the combined intake.

[b]Based on a MOE > 100 for target species for fattening, calculated as the ratio of the reference point (NOAEL of 10 mg/kg bw per day) to the combined intake.

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

The FEEDAP Panel considers that the use in water for drinking alone or in combination with the use in feed should not exceed the daily amount that is considered of low concern/no concern when consumed via feed alone.

The use of citronella oil in animal feed is not expected to be of concern for consumers.

Citronella oil from *C. nardus* should be considered as irritant to skin and eyes, and as a dermal sensitiser. When handling the essential oil, exposure of unprotected users to methyleugenol may occur. Therefore, to reduce the risk, the exposure of the users should be minimised.

The use of citronella oil under the proposed conditions of use is not expected to pose a risk to the environment.

Since the leaves of *C. nardus* and their essential oil 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 | RECOMMENDATION

The specification should ensure that citronella oil (*C. nardus*) contains ≤ 1% methyleugenol.

6 | DOCUMENTATION PROVIDED TO EFSA/CHRONOLOGY

Date	Event
28/10/2010	Dossier received by EFSA. Botanically defined flavourings from Botanical Group 07 – Geraniale, Myrtales, Poales for all animal species and categories. Submitted by Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)
09/11/2010	Reception mandate from the European Commission
21/12/2010	Application validated by EFSA – Start of the scientific assessment
22/03/2011	Comments received from Member States
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

(Continued)

Date	Event
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
20/01/2014	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
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: on broom teatree oil, geranium oil, bay oil and vetiveria oil
17/12/2019	EFSA informed the applicant that the evaluation process restarted
18/12/2019	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*
31/01/2023	Reception of supplementary information from the applicant (partial dataset: citronella oil) - Scientific assessment remains suspended
06/06/2023	Reception of an amendment of the Evaluation report of the European Union Reference Laboratory for Feed Additives related to geranium rose oil, eucalyptus oil, citronella oil and clove oil
01/03/2024	Reception of an amendment of the Evaluation report of the European Union Reference Laboratory for Feed Additives related to citronella oil, melaleuca oil, niaouli oil, tea tree oil, eucalyptus tincture, clove tincture
26/03/2024	The application was split and a new EFSA-Q-2024-00190 was assigned to the additive included in the present assessment. Scientific assessment re-started for the additive included in the present assessment
17/04/2024	Opinion adopted by the FEEDAP Panel on citronella oil (EFSA-Q-2024-00190). End of the Scientific assessment for the additive included in the present assessment. The assessment of other additives in BGD 07 is still ongoing

ABBREVIATIONS

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

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2010-01282 (new EFSA-Q-2024-00190)

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