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Safety and efficacy of a feed additive consisting of an essential oil from the herbaceous parts of *Pelargonium graveolens* L'Hér. (geranium rose oil) for all animal species (FEFANA asbl)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Mojca Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Paul Brantom, Andrew Chesson, Johannes Westendorf, Paola Manini and Birgit Dusemund

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of an essential oil obtained from the herbaceous parts of *Pelargonium graveolens* L'Hér. (geranium rose oil), when used as a sensory additive 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 use of geranium rose oil is safe up to the maximum proposed use levels of 5 mg/kg complete feed for all animal species. The FEEDAP Panel considered that the use in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed. No concerns for consumers were identified following the use of geranium rose oil up to the maximum proposed use level in feed. The additive under assessment should be considered as irritant to skin and eyes, and as a skin and respiratory sensitiser. The use of geranium rose oil at the proposed use level in feed was not expected to pose a risk to the environment. Since *P. graveolens* 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: sensory additives, flavouring compounds, *Pelargonium graveolens* L'Hér., geranium rose oil, citronellol, geraniol, safety

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Correspondence: feedap@efsa.europa.eu

Panel members: Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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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, citronella oil, lemongrass oil and vetiveria oil) belonging to botanically defined group (BDG) 07 – *Geraniales, Myrtales, Poales* when used as feed additives 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: geranium rose oil from *Pelargonium graveolens* L'Hér.[6] for all animal species.

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 product geranium rose oil from *P. graveolens*, when used under the proposed conditions of use (see Section 3.2.4).

1.2. Additional information

Geranium rose oil from *Pelargonium graveolens* L'Herit. Ex Ait. 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.

There is no specific EU authorisation for any *P. graveolens* preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008[7] flavourings preparations produced from food or food ingredients with flavouring properties, may be used without an evaluation and approval

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] On 13/03/2013, EFSA was informed by the applicant that the applicant company changed to FEFANA asbl, Avenue Louise 130 A, Box 1, 1050 Brussels, Belgium.
[3] On 27 February 2019, EFSA was informed by the applicant about the withdrawal of the applications on broom teatree 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 nabbusa tincture and allspice oil.
[5] Register of feed additives, Annex II, withdrawn by OJ L162, 10.05.2021, p. 5.
[6] Accepted name: *Pelargonium graveolens* L'Hér.; synonims: *Pelargonium graveolens* L'Herit. Ex Ait.
[7] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Regulation (EC) No 1601/91 of the Council, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34.

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'.

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). The flavouring compounds currently authorised for feed[8] and/or food[9] use, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000[10] and the corresponding EFSA opinion are listed in Table 1.

Table 1: 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 (common 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	Octanal	05.009	2013
		Methyl geranate[(a)]	09.643	2011a, CEF 2013, CEF
03	α, ß-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters	Geraniol	02.012	2016a
		Neral	05.170	
		trans-3,7-Dimethylocta-2,6-dienal (geranial)	05.188	
		Geranyl acetate	09.011	
		Geranyl butyrate	09.048	
		Geranyl formate	09.076	
		Neryl formate	09.112	
		Geranyl propionate	09.128	
		Geranyl hexanoate[(a)]	09.067	2009, CEF
		Geranyl isovalerate[(a)]	09.453	
		Citronellyl 2-methylbut-2-enoate[(a)]	09.340	2010a, CEF
		Geranyl 2-methylcrotonate[(a)]	09.383	
04	Non-conjugated and accumulated unsaturated straight-chain and branched-chain aliphatic primary alcohols, aldehydes, acids, acetals and esters	Citronellol	02.011	2016b
		Citronellyl acetate	09.012	
		Citronellyl butyrate	09.049	
		Citronellyl formate	09.078	
		Citronellyl propionate	09.129	
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	Isopulegol	02.067	2020
		Nonan-2-one	07.020	2015a
		6-Methylhepta-3,5-dien-2-one	07.099	

[8] 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

[9] 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.

[10] 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 180, 19.7.2000, p. 8.

CG	Chemical Group	Product – EU register name (common name)	FLAVIS No	EFSA opinion,* Year
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a
		α-Terpineol	02.014	
		4-Terpinenol	02.072	
		Myrcenol[(a),(b)]	02.185	2011b, CEF 2015a, CEF
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	Menthol[(c)]	02.015	2016c, 2020
		d,l-Isomenthone (*cis*-menthone)	07.078	
		trans-Menthone[(d)]	07.176	
		Menthyl acetate[(e)]	09.016	
13	Furanones and tetrahydrofurfuryl derivatives	Linalool oxide[(f)]	13.140	2012b
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012c, 2021
		2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran (rose oxide)[(g)]	13.037	2012c
		2,6,6-Trimethyl-2-vinyltetrahydropyran[(a)]	13.094	2011c, CEF
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	1-Isopropyl-4-methylbenzene (p-cymene)	01.002	2015b
		α-Phellandrene	01.006	
		1-Isopropenyl-4-methylbenzene	01.010	
		α-Terpinene	01.019	
		γ-Terpinene	01.020	
		d-Limonene	01.045	
		Pin-2(10)-ene (β-pinene)	01.003	2016d
		Pin-2(3)-ene (α-pinene)	01.004	
		β-Caryophyllene	01.007	
		Valencene	01.017	
		δ-Cadinene[(a),(b)]	01.021	2011d, CEF
		Germacra-1(10),4(14),5-triene[(a),(b)]	01.042	
		3,7,10-Humulatriene[(a),(b)]	01.043	
		α-Muurolene[(a),(b)]	01.052	
		β-Phellandrene[(a),(b)]	01.055	
		cis-3,7-Dimethyl-1,3,6-octatriene *cis*-β-Ocimene[(a)]	01.064	2015b, CEF
		β-Bourbonene[(a)]	01.024	2015c, CEF

*: FEEDAP opinion unless otherwise indicated.
(a): Evaluated for use in food only. According to Regulation (EC) 1565/2000, flavourings evaluated by JECFA before 2000 are not required to be re-evaluated by EFSA.
(b): 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, 2010b). No longer authorised for use as flavours in food, as the additional toxicity data requested (EFSA CEF Panel, 2011d) were not submitted and the CEF Panel was unable to complete its assessment.
(c): Menthol [02.105]: The stereochemistry is not specified but the analytical data provided refer to (−)-menthol or l-menthol (EFSA FEEDAP Panel, 2016a). On 7 March 2017, the applicant clarified that d,l-menthol [02.218] and menthol [02.015] are the same additive. The same FLAVIS number [02.015] can be adequately used to identify the racemate and its isomeric forms (EFSA FEEDAP Panel, 2020).
(d): *trans*-Menthone [07.176]: menthone exists only as *trans*-isomer. Referred in the opinion to as menthone.
(e): Menthyl acetate [09.016]: JECFA evaluated menthyl acetate (CAS No 16409-45-3 which does not specify isomer). In 2013, the CAS No in Register was replaced by 16409-45-3 (EFSA FEEDAP Panel, 2016a).
(f): Linalool oxide [13.140]: A mixture of *cis*- and *trans*-linalool oxide (5-ring) was evaluated.
(g): Rose oxide [13.037]: A mixture of diastereomers (*cis*- and *trans*-rose oxide) was evaluated, composition of the mixture not specified.

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[11] in support of the authorisation request for the use of geranium rose oil from *P. graveolens* as a feed additive. The dossier was received on 19 January 2023 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00034.[12]

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

Many of the components of the essential oil under assessment have been already evaluated by the FEEDAP Panel as chemically defined flavourings. The applicant submitted a written agreement to use the data submitted for the assessment of chemically defined flavourings (dossiers, publications and unpublished reports) for the risk assessment of preparations belonging to BDG 7, including the one under assessment.[13]

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. The evaluation report is related to the methods of analysis for each feed additive included the group BDG 07 (Geraniales, Myrtales, Poales). During the assessment, upon request from EFSA, the EURL issued a first amendment of the original report, which included the additive under assessment, *geranium rose oil*.[14] In particular, the EURL recommended a method based on gas chromatography coupled with flame ionisation detection (GC-FID) for the quantification of the phytochemical marker *citronellol* in *geranium rose oil*.[15]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of geranium rose oil from *P. graveolens* is in line with the principles laid down in Regulation (EC) No 429/2008[16] and the relevant guidance documents: Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA SC, 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, 2012d), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012e), 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 harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA SC, 2019a), Statement on the genotoxicity assessment of chemical mixtures (EFSA SC, 2019b), Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA SC, 2019c).

3. Assessment

The additive under assessment, geranium rose oil, is an essential oil obtained from the herbaceous parts of *Pelargonium graveolens* L'Hér., intended for use as a sensory additive (functional group: flavouring compounds) in feed and in water for drinking for all animal species.

[11] FEED dossier reference: FAD-2010-0219.
[12] The original application EFSA-Q-2010-01282 was split on 19/01/2023 and a new EFSA-Q-2023-00034 was generated.
[13] Technical dossier/Supplementary information February 2023/Letter dated 31/01/2023.
[14] Preparations included in the first amendment: geranium rose oil, eucalyptus oil, lemongrass oil and clove oil.
[15] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0219_en
[16] 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.

3.1. Origin and extraction

Pelargonium graveolens L'Her., commonly called the rose-scented or sweet-scented geranium, is an evergreen perennial herbaceous plant belonging to the Geraniaceae family. It is native to South Africa but is now widely cultivated for commercial purposes and as an ornamental garden plant.

The major commercial use is as a source of an essential oil which is used in the perfume trade as a substitute for the more expensive attar of roses, obtained from the petals of various *Rosa* spp. The actual identity of the pelargoniums described as *P. graveolens* or by the synonym *Pelargonium asperum* Ehrh. Ex Willd used for commercial oil production is conjectural, since numerous cultivars and hybrids exist and are used by the industry. For this reason, it is increasingly common to refer only to the pelargonium Rosat group of cultivars rather than a specific species. As a consequence, all pelargonium distillates are covered by a single CAS (8000-46-2), EINECS (290-140-0) and FEMA (2508) numbers regardless of their specific botanical origin.

The present additive is extracted by steam distillation from the herbaceous parts of plants described as *P. graveolens* grown in North Africa. The volatile constituents are condensed and then separated from the aqueous phase by decantation.

3.2. Characterisation

3.2.1. Characterisation of geranium rose oil

The essential oil under assessment is a yellow to amber clear slightly viscous liquid with a characteristic odour. In five batches of the additive, the refractive index (20°C) ranged between 1.464 and 1.469 (specification: 1.462–1.472).[17] Geranium rose oil is identified with the single Chemical Abstracts Service (CAS) number 8000-46-2, the European Inventory of Existing Chemical Substances (EINECS) number 290-140-0, the Flavor Extract Manufacturers Association (FEMA) 2508 and the Council of Europe (CoE) number 324.[18]

For geranium rose oil, the product specifications are based on the standard developed by the International Organisation for Standardization (ISO) 4371:2012 for essential oil of geranium (*Pelargonium* × ssp.),[19] adapted to reflect the concentrations of selected volatile components. Six components contribute to the specification as shown in Table 2, with citronellol selected as the phytochemical marker. Analysis of five batches of the additive showed compliance with these specifications when analysed by GC-FID and expressed as percentage of gas chromatographic peak area (% GC area).[20]

Table 2: Major constituents of the essential oil from the herbaceous parts of *Pelargonium graveolens* L'Hér. as defined by specifications and batch to batch variation based on the analysis of five batches by gas chromatography with flame ionisation detector (GC-FID). The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%

Constituent	CAS No	FLAVIS No	% GC area		
EU register name			Specification[(a)]	Mean	Range
Citronellol	106-22-9	02.011	25–36	32.3	31.3–34.6
Geraniol	106-24-1	02.012	10–18	15.1	14.0–15.4
Citronellyl formate	105-85-1	09.078	4–9	7.28	6.97–7.42
Linalool	78-70-6	02.013	4–8.5	5.52	4.59–5.88
d,l-Isomenthone (*cis*-menthone)	491-07-6	07.078	4–8	6.04	5.94–6.16
2-(2-Methylprop-1-enyl)-4-methyl tetrahydropyran (rose oxide)[(b)]	16409-43-1	13.037	0.7–1.5	1.05	1.00–1.15

[17] Technical dossier/Supplementary information May 2022/Annex_II_SIn_Reply_geranium_rose_oil_COA_chromatograms.
[18] A number of entries were found at https://echa.europa.eu/home: 'Geranium oil': EINECS 616–774-3; CAS 8000-46-2'Pelargonium graveolens, ext.': EINECS 290–140-0; CAS 90082–51-2
[19] Technical dossier/Supplementary information May 2022/Annex_III_SIn_reply_geranium_rose_oil_ ISO_4731_2012.
[20] Technical dossier/Supplementary information May 2022/SIn_reply_geranium_rose_oil/Table_3.

EU: European Union; CAS No: Chemical Abstracts Service number; FLAVIS No: EU Flavour Information System numbers.
(a): Specifications defined based on GC-FID analysis.
(b): 2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran, hereinafter referred to as rose oxide [13.037]: A mixture of diastereomers (*cis*- and *trans*-rose oxide) was evaluated, composition of the mixture not specified.

The applicant provided the full characterisation of the five batches by gas chromatography–mass spectrometry (GC–MS).[21] In total, up to 87 constituents were detected, 80 of which were identified and accounted on average for 99.4% (99.2–100%) of the % GC area. The six compounds indicated in the product specifications account for about 56.1% on average (range 55.7–56.6%) of the GC area. Besides the six compounds indicated in the product specifications, 22 other compounds were detected at individual levels > 0.5% and are listed in Table 3. These 28 compounds together account on average for 87.7% (87.2–88.7%) of the % GC area. The remaining 52 compounds (ranging between 0.01% and 0.47%) and accounting for 11.8% of the % GC area are listed in the footnote.[22] Based on the available data on the characterisation, geranium rose oil is considered a fully defined mixture (EFSA SC, 2019a).

Table 3: Constituents of the essential oil from the herbaceous parts of *Pelargonium graveolens* L'Hér. accounting for > 0.5% of the composition (based on the analysis of five batches by gas chromatography–mass spectrometry). The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%

Constituent EU register name	CAS No	FLAVIS No	% GC area	
			Mean	Range
Citronellol	106-22-9	02.011	24.91	24.07–26.24
Geraniol	106-24-1	02.012	12.40	11.62–12.71
Citronellyl formate	105-85-1	09.078	7.31	7.05–7.46
Linalool	78-70-6	02.013	4.39	3.64–4.69
d,l-Isomenthone (*cis*-menthone)	491-07-6	07.078	5.91	5.78–5.99
2-(2-Methylprop-1-enyl)-4-methyl tetrahydropyran (rose oxide)[(a)]	16409-43-1	13.037	1.16	1.12–1.25
10-epi-γ-Eudesmol	15051-81-7	–	7.59	7.49–7.91
Geranyl formate	105-86-2	09.076	3.13	2.62–3.32
δ-Cadinene	29350-73-0	01.021	2.23	2.10–2.43
Germacra-1(10),4(14),5-triene	23986-74-5	01.042	1.93	1.63–2.69
Geranyl 2-methylcrotonate	7785-33-3	09.383	1.68	1.51–1.78
β-Caryophyllene	87-44-5	01.007	1.54	1.49–1.64
Phenethyl 2-methylcrotonate	55719-85-2	09.496	1.51	1.50–1.53
Geranyl butyrate	106-29-6	09.048	1.48	1.41–1.52
β-Bourbonene	5208-59-3	01.024	1.20	0.15–1.51
trans-Menthone[(b)] (menthone)	89-80-5	07.176	0.75	0.55–1.16
α-Gurjunene	489-40-7	–	0.74	0.70–0.78
α-Copaene	3856-25-5	–	0.72	0.56–0.80
Geranyl acetate	105-87-3	09.011	0.71	0.46–1.51

[21] Technical dossier/Supplementary information May 2022/Annex_II_SIn_Reply_geranium_rose_oil_COA_chromatograms.
[22] Additional constituents:constituents (n = 23) between < 0.5 and ≥ 0.2%: α-muurolene, *trans*-rose oxide, neral, α-agarofuran, citronellyl propionate, γ-elemene, valencene, 3,7,10-humulatriene, γ-cadinene, pin-2(3)-ene (α-pinene), citronellyl acetate, α-cubebene, citronellyl 2-methylbut-2-enoate, geranyl hexanoate, alloaromadendrene, spathulenol, T-muurolol, d-limonene, 1,10-di-epi-cubenol, 1-epi-cubenol, γ-muurolene, menthol and *cis*-linalool oxide (5-ring), constituents (n = 11) between < 0.2 and ≥ 0.1%: β-gurjunene, *trans*-cadina-1,4-diene, γ-eudesmol, *trans*-linalool oxide (5-ring), geranyl isovalerate, β-phellandrene, neryl formate, *trans*-3,7-dimethyl-1,3,6-octatriene, 6-methylhepta-3,5-dien-2-one, isogeraniol and 1-isopropyl-4-methylbenzene,constituents (n = 18) between < 0.1 and ≥ 0.01%: *cis*-3,7-dimethyl-1,3,6-octatriene, pin-2(10)-ene (β-pinene), isopulegol, menthyl acetate, 2,6,6-trimethyl-2-vinyltetrahydropyran, α-phellandrene, 4-terpinenol, (Z)-dehydroxylinalool oxide, citronellal, methyl geranate, (E)-dehydroxylinalool oxide, 1-isopropenyl-4-methylbenzene, nonan-2-one, γ-yerpinene, myrcenol, octanal, 1,8-cineole and α-terpinene.

Constituent EU register name	CAS No	FLAVIS No	% GC area	
			Mean	Range
β-Eudesmol	473-15-4	–	0.70	0.61–0.86
Geranyl propionate	105–90-8	09.128	0.70	0.09–0.87
α-Amorphene	483-75-0	–	0.67	0.51–0.85
Citronellyl butyrate	141-16-2	09.049	0.67	0.57–0.75
trans-3,7-Dimethylocta-2,6-dienal	141-27-5	05.188	0.60	0.58–0.62
Guaia-6,9-diene	–	–	0.59	0.56–0.63
γ-Selinene	515-17-3	–	0.58	0.14–0.85
trans-Cadina-1(6),4-diene	931410-54-7	–	0.57	0.47–0.87
α-Terpineol	98-55-5	02.014	0.56	0.41–0.63
Total			31.58	31.22–32.34[(c)]

EU: European Union; CAS No: Chemical Abstracts Service number; FLAVIS No: EU Flavour Information System numbers.
(a): 2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran, hereinafter referred to as rose oxide [13.037]: A mixture of diastereomers (*cis*- and *trans*-rose oxide) was evaluated, composition of the mixture not specified.
(b): *trans*-Menthone [07.176]: menthone exists only as *trans*-isomer. Hereinafter referred to as menthone.
(c): The values given for the total are the lowest and the highest values of the sum of the components in the five batches analysed.

The applicant performed a literature search for information on the chemical composition of *P. graveolens* and its preparations and the presence of compounds of known concern.[23] Two of 60 references reported the presence of substances of concern. These were α- and β-sinensal (1% and 0.5%, respectively) in leaf essential oil from Iran (Azarafshan et al., 2019), estragole (0.8%) in an essential oil from *P. graveolens* (a commercial product from an Egyptian manufacturer, parts of the plant not specified, El-Garawani et al., 2019). The presence of these compounds was not reported by other authors, and they were not detected by GC–MS in the essential oil under assessment (limit of detection, LOD 0.005%).

3.2.2. Impurities

The applicant referred to the 'periodic testing' of some representative flavourings premixtures for mercury, cadmium and lead, arsenic, fluoride, dioxins and polychlorinated biphenyls (PCBs), organo-chloride pesticides, organo-phosphorus pesticides, aflatoxins (B1, B2, G1, G2) and ochratoxin A. However, no data have been provided on the presence of these impurities. Since geranium rose oil 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 geranium rose oil is stated to be at least 12 months, when stored in tightly closed containers under standard conditions (in a cool, dry place protected from light).[24] However, no data supporting this statement were provided.

3.2.4. Conditions of use

Geranium rose oil is intended to be added to feed and water for drinking for all animal species without a withdrawal period. The maximum proposed use level in complete feed for the different target species is 5 mg/kg. No use level has been proposed by the applicant for the use in water for drinking.

3.3. Safety

The assessment of safety of geranium rose oil is based on the maximum use levels proposed by the applicant in complete feed (5 mg/kg complete feed).

[23] Technical dossier/Supplementary information May 2022/Literature search_geranum_rose_oil.
[24] Technical dossier/Section II.

Many of the components of geranium rose oil, accounting for about 77% of the GC peak area, have been previously assessed and considered safe for use as flavourings, and are currently authorised for use in food[9] without limitations and for use in feed[8] at individual use levels higher than those resulting from the intended use of the essential oil in feed. The list of the compounds already evaluated by the EFSA Panels is given in Table 1 (see Section 1.2). The FEEDAP Panel considers that the conclusions of the assessment of linalool oxide [13.140] evaluated in CG 13 (EFSA FEEDAP Panel, 2012b) apply to the isomers *cis*- and *trans*-linalool oxide present in the additive. Similarly, the conclusion for rose oxide [13.037], evaluated in CG 16 as a mixture of diastereomers (EFSA FEEDAP Panel, 2012c), also apply to *cis*- and *trans*-rose oxide.

Five compounds listed in Table 1, δ-cadinene [01.021], germacra-1(10),4(14),5-triene [01.042], 3,7,10-humulatriene [01.043], α-muurulene [01.052] and β-phellandrene [01.055], have been evaluated in FGE25.Rev2 (EFSA CEF Panel, 2011d) by 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, 2010a,b). For these compounds, for which there is no concern for genotoxicity, EFSA requested additional subchronic toxicity data (EFSA CEF Panel, 2011d). In the absence of such toxicological data, the EFSA CEF Panel was unable to complete its assessment. As a result, these compounds are not authorised for use as flavours in food. In the absence of toxicity data, the FEEDAP Panel applied the threshold of toxicological concern (TTC) approach or read-across from structurally related substances, following the approach recommended in the Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA SC, 2019a).

Twenty-four additional components have not been previously assessed for use as flavourings. The FEEDAP Panel notes that 18 of them[25] accounting together for 16% of the GC area are aliphatic mono- or sesquiterpenes structurally related to flavourings already assessed in CG 3, 6 and 31 and a similar metabolic and toxicological profile is expected. These lipophilic compounds are expected to be rapidly absorbed from the gastrointestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted (EFSA FEEDAP Panel, 2012a,b, 2016a,d).

The remaining six compounds, myrcenol, spathulenol, T-muurolol, (Z)-dehydroxylinalool oxide, (E)-dehydroxylinalool oxide and α-agarofuran, were screened with the Organization for Economic Co-operation and Development (OECD) Quantitative Structure–Activity Relationship (QSAR) Toolbox. No alert was identified for *in vitro* mutagenicity, for genotoxic and non-genotoxic carcinogenicity and for other toxicity endpoints for myrcenol, spathulenol, T-muurolol, whereas for (Z)-dehydroxylinalool oxide, (E)-dehydroxylinalool oxide and α-agarofuran structural alerts were due to the presence of the vinyl/allyl ether and the oxolane group. For these substances, predictions of mutagenicity by Ames test (with and without S9) were made by 'read-across' analyses of data available for similar substances to the target compounds (i.e. analogues obtained by categorisation). Mutagenicity read-across-based predictions were all found negative for all the substances.[26] On this basis, the alerts raised were discounted.

3.3.1. Safety for the target species

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

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

As the additive under assessment is a fully defined mixture (the identified components represent > 99.2% 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.

[25] Isogeraniol (CG 3); 1,10-di-epi-cubenol, 10-epi-γ-eudesmol, 1-epi-cubenol, γ-eudesmol, β-eudesmol (CG 6); *trans*-3,7-dimethyl-1,3,6-octatriene, α-cubebene, α-copaene, β-gurjunene, guaia-6,9-diene, α-gurjunene, alloaromadendrene, trans-cadina-1(6),4-diene, γ-muurolene, γ-selinene, γ-cadinene, *trans*-cadina-1,4-diene and α-amorphene (CG 31).

[26] Technical dossier/Supplementary information May 2022/Annex VI_SIn_reply_geranium rose_oil_QSAR.

Based on considerations related to structural and metabolic similarities, the components were allocated to 11 assessment groups, corresponding to the chemical groups (CGs) 1, 3, 4, 5, 6, 8, 13, 15, 16 and 31, as defined in Annex I of Regulation (EC) No 1565/2000.[27] For CG 31 ('aliphatic and aromatic hydrocarbons'), subassessment groups as defined in Flavouring Group Evaluation 25 (FGE.25) and FGE.78 were established (EFSA CEF Panel, 2015b,c). The allocation of the components to the (sub-)assessment groups is shown in Table 4 and in the corresponding footnote.

For each component in the assessment group, exposure in target animals was estimated considering the use levels in feed, the percentage of the component in the oil and the default values for feed intake according to the guidance on the safety of feed additives for target species (EFSA FEEDAP Panel, 2017b). Default values on body weight (bw) are used to express exposure in terms of mg/kg bw. The intake levels of the individual components calculated for chickens for fattening, the species with the highest ratio of feed intake/bw per day, are shown in Table 4.

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 group, toxicological data were available to derive no observed adverse effect level (NOAEL) values. 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 group with no available NOAEL or, if sufficient evidence were available for members of a (sub-)assessment group, to derive a (sub-) assessment group NOAEL.

Toxicological data for subchronic studies, from which NOAEL values could be derived, were available for acetaldehyde [05.001], the representative compound in CG 1 (EFSA FEEDAP Panel, 2013), for citral [05.020] the representative compound in CG 3 (EFSA FEEDAP Panel, 2016a), for citronellol [02.011] in CG 4 (EFSA FEEDAP Panel, 2016b), for isopulegol [02.067] in CG 5 (EFSA FEEDAP Panel, 2020), linalool [02.013] and terpineol [02.230][28] in CG 6 (EFSA FEEDAP Panel, 2012a), menthol [02.015] in CG 08 (EFSA SC, 2014), 1,8-cineole in CG 16 (EFSA FEEDAP Panel, 2021), d-limonene [01.045], *p*-cymene [01.002], myrcene [01.008] and β-caryophyllene [01.007] in CG 31 (EFSA FEEDAP Panel, 2015b,c).

The NOAEL of 120 mg/kg bw per day for acetaldehyde [05.001] was selected as reference point for CG 1 compounds. Considering the structural and metabolic similarities, the NOAELs of 345 mg/kg bw per day for citral [05.020] and 50 mg/kg bw per day for citronellol [02.012] were selected as the reference points for CG 3 and 4, respectively.

For the subgroup of terpinyl derivatives in CG 6, i.e. α-terpineol [02.072], 4-terpinenol [02.072], 10-epi-γ-eudesmol, γ-eudesmol, β-eudesmol, 1-epi-cubenol and 1,10-di-epi-cubenol, 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].

In CG 8, the NOAEL of menthol [02.015] was applied to menthyl acetate [09.016], d,l-isomenthone [07.078] and menthone [07.176]. For the two latter compounds, the NOAEL of menthol was halved to take into account additional uncertainty in read across.

For rose oxide, the applicant provided a study from which a NOAEL of 100 mg/kg bw per day was identified (Api et al., 2017). The NOAEL is based upon application of a threefold adjustment factor to a dose of 300 mg/kg bw per day, which was without adverse effect in a 28-day study. The NOAEL is applied to the isomers *cis*- and *trans*-rose oxide.

The NOAELs for the representative compounds of CG 31, d-limonene [01.045], myrcene [01.008], *p*-cymene [01.002] and β-caryophyllene [01.007] were applied, respectively, using read-across to the compounds within subassessment groups III, IVe and V (EFSA CEF Panel, 2015a,b). The NOAEL for myrcene was extrapolated to myrcenol in CG 6.

[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 180,19.7.2000, p. 8.

[28] 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] (or δ-terpineol). The specification for terpineol [02.230] covers α-, β-, γ and δ-terpineol. Composition of mixture: 55–75% α-terpineol, 16–23% γ-terpineol, 1–10% *cis*-β-terpineol, 1–13% *trans*-β-terpineol and 0–1% δ-terpineol (EFSA CEF Panel, 2015c) FGE.18Rev 3.

For the remaining compounds,[29] NOAEL values identified in toxicity studies performed with the compounds under assessment were not available and read-across was not possible. Therefore, the threshold of toxicological concern (TTC) approach was applied (EFSA FEEDAP Panel, 2012d, 2017b).

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 4.

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 SC, 2019a). An MOE(T) > 100 allowed for interspecies differences 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.[30]

The approach to the safety assessment of geranium rose oil for the chickens for fattening is summarised in Table 4.

Table 4: Compositional data, intake values (calculated for chickens for fattening at 5 mg/kg complete feed), reference points and margin of exposure (MOE) for the individual components of geranium rose oil classified according to assessment groups

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/day**	–	**mg/kg bw/day**	–	–
CG 1								
Methyl geranate	09.643	0.05	0.003	0.0002	I	*3*	12,377	
CG 3								
Geraniol	02.012	12.71	0.636	0.0571	(I)	345	6,045	
Geranyl formate	09.076	3.32	0.166	0.0149	(I)	345	23,144	
Geranyl 2-methylcrotonate	09.383	1.78	0.089	0.0080	(I)	345	43,204	
MOET CG 3								4,315
CG 4								
Citronellol	02.011	26.24	1.312	0.1178	(I)	50	425	
Citronellyl formate	09.078	7.46	0.373	0.0335	(I)	50	1,494	
Citronellyl butyrate	09.049	0.75	0.038	0.0034	(I)	50	14,852	
Citronellyl acetate	09.012	0.74	0.037	0.0033	(I)	50	15,073	
Citronellyl propionate	09.129	0.51	0.026	0.0023	(I)	50	21,842	

[29] Methyl geranate (CG 1); nonan-2-one, 6-methylhepta-3,5-dien-2-one (CG 5); spathulenol, T-muurolol, myrcenol (CG 6); *cis*- and *trans*-linalool oxide (CG 13); phenethyl 2-methylcrotonate (CG 15); 2,6,6-trimethyl-2-vinyltetrahydropyran, (Z)-dehydroxylinalool oxide, (E)-dehydroxylinalool oxide, α-agarofuran (CG 16); γ-elemene, 1-isopropenyl-4-methylbenzene, 3,7,10-humulatriene, germacra-1(10),4(14),5-triene (CG 31).

[30] Compounds included in the assessment groups but not reported in the table: octanal (CG 1); geranyl butyrate, geranyl acetate, geranyl propionate, *trans*-3,7-dimethylocta-2,6-dienal, neral, citronellyl 2-methylbut-2-enoate, geranyl hexanoate, geranyl isovalerate, neryl formate and isogeraniol (CG 3); citronellal (CG 4); isopulegol (CG 5); β-eudesmol, α-terpineol, 1,10-di-epi-cubenol, 1-epi-cubenol, γ-eudesmol, 4-terpinenol and myrcenol (CG 6); menthol and menthyl acetate (CG 8); 1,8-cineole (CG 16); *cis*-3,7-dimethyl-1,3,6-octatriene and *trans*-3,7-dimethyl-1,3,6-octatriene (CG 31, II); d-limonene, β-phellandrene, α-phellandrene, α-terpinene and γ-terpinene (CG 31, III); p-cymene (CG 31, IVe); *trans*-cadina-1(6),4-diene, γ-selinene, α-amorphene, α-copaene, α-gurjunene, guaia-6,9-diene, α-cubebene, valencene, γ-muurolene, α-muurolene, α-pinene, γ-cadinene, alloaromadendrene, *trans*-cadina-1,4-diene, β-gurjunene and β-pinene (CG 31, V).

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/day**	–	**mg/kg bw/day**	–	–
MOET CG 4								312
CG 5								
Nonan-2-one	07.020	0.04	0.002	0.0002	II	*0.91*	5,632	
6-Methylhepta-3,5-dien-2-one	07.099	0.11	0.006	0.0005	II	*0.91*	1,843	
MOET CG 5								1,389
CG 6								
10-epi-γ-Eudesmol	n.a.	7.59	0.396	0.0355	(III)	250	7,041	
Linalool	02.013	4.39	0.234	0.0210	(I)	**117**	5,561	
Spathulenol	n.a.	0.29	0.016	0.0015	I	*3*	2,056	
T-Muurolol	n.a.	0.29	0.034	0.0030	I	*3*	992	
MOET CG 6								550
CG 8								
d,l-Isomenthone	07.078	5.99	0.031	0.0027	(II)	187[d]	6,953	
Menthone	07.176	1.16	0.023	0.0020	(II)	187[d]	35,822	
MOET CG 8								5,686
CG 13								
cis-Linalool oxide	n.a.	0.26	0.013	0.0012	II	*0.91*	789	
trans-Linalool oxide	n.a.	0.16	0.008	0.0007	II	*0.91*	1267	
MOET CG 13								486
CG 15								
Phenethyl 2-methylcrotonate	09.496	1.53	0.076	0.0069	I	*3*	437	
CG 16								
cis-Rose oxide	n.a.	1.25	0.062	0.0056	(II)	**100**	17,837	
trans-Rose oxide	n.a.	0.54	0.027	0.0024	(II)	100	41,564	
α-Agarofuran	n.a.	0.47	0.023	0.0021	II	*0.91*	436	
2,6,6-Trimethyl-2-vinyltetrahydropyran	13.094	0.08	0.004	0.0004	II	*0.91*	2,503	
(Z)-Dehydroxy linalool oxide	n.a.	0.05	0.003	0.0002	II	*0.91*	3,899	
(E)-Dehydroxy linalool oxide	n.a.	0.10	0.005	0.0004	II	*0.91*	2,069	
MOET CG 16								285
CG 31, III (Cyclohexene hydrocarbons)								
γ-Elemene	n.a.	0.54	0.027	0.0024	I	*3*	1,247	
CG 31, IVe (Benzene hydrocarbons, alkyl)								
1-Isopropenyl-4-methylbenzene	n.a.	0.05	0.002	0.0002	I	*3*	14,220	
CG 31, V (Bi-, tricyclic, non-aromatic hydrocarbons)								
δ-Cadinene	01.021	2.43	0.122	0.0109	(I)	222	20,328	
β-Caryophyllene	01.007	1.64	0.082	0.0073	(I)	**222**	30,213	

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/day**	–	**mg/kg bw/day**	–	–
β-Bourbonene	01.024	1.51	0.076	0.0068	(I)	222	32,754	
MOET CG 31, V								8,863
CG 31, VI (Macrocyclic non-aromatic hydrocarbons)								
Germacra-1(10),4 (14),5-triene	01.042	2.69	0.135	0.0121	I	*3*	I	
3,7,10-Humulatriene	01.043	0.41	0.021	0.0018	I	*3*	I	
MOET CG 31, VI								215

(a): Intake calculations for the individual components are based on the use level of 5 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.
(d): The NOAEL of 375 mg/kg bw per day for menthol was halved to take into account the uncertainty in read across.

As shown in Table 4, the MOET was > 100 for all assessment groups. From the lowest MOE of 215 (for CG 31, VI) in chickens for fattening, the MOE was calculated for the other target species considering the respective daily feed intake/kg bw and conditions of use. The results are summarised in Table 5.

Table 5: Combined margin of exposure (MOET) for the assessment group CG 31, VI (macrocyclic non-aromatic hydrocarbons) calculated for the different target animal categories at the proposed use level in feed

Animal category	Body weight (kg)	Feed intake (g DM/day)	Proposed use level (mg/kg feed)[1]	Lowest MOET
Chicken for fattening	2	158	5	215
Laying hen	2	106	5	320
Turkey for fattening	3	176	5	288
Piglet	20	880	5	386
Pig for fattening	60	2,200	5	459
Sow lactating	175	5,280	5	566
Veal calf (milk replacer)	100	1,890	5	894
Cattle for fattening	400	8,000	5	960
Dairy cow	650	20,000	5	548
Sheep/goat	60	1,200	5	849
Horse	400	8,000	5	849
Rabbit	2	100	5	340
Salmon	0.12	2.1	5	944
Dog	15	250	5	999
Cat[2]	3	60	5	849
Ornamental fish	0.012	0.054	5	3,397

(1): Complete feed containing 88% DM, milk replacer 94.5% DM.
(2): The MOET for cats is increased to 500 because of the reduced capacity of glucuronidation.

Table 5 shows that for all species, the MOET exceeds the value of 100. Because glucuronidation is an important metabolic reaction to facilitate the excretion of the components of the essential oil, the use of geranium rose oil as additive in cat feed needs a wider margin of exposure. 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 and Greenblatt, 1997; Lautz et al., 2021), the use of geranium rose oil as additive in cat feed needs a wider margin of exposure. An MOET of 500 is considered adequate. For all target species, no safety concern was identified for geranium rose oil when used as feed additive up to the maximum proposed use level of 5 mg/kg complete feed.

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 combination with use in feed should not exceed the daily amount that is considered safe when consumed via feed alone (EFSA FEEDAP Panel, 2010).

3.3.1.1. Conclusions on safety for the target species

The use of geranium rose oil is considered as safe up to the maximum proposed use level in feed of 5 mg/kg complete feed for all animal species.

The FEEDAP Panel considers that 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 alone.

3.3.2. Safety for the consumer

Geranium rose oil originating from the leaves and stems of *Pelargonium graveolens* and several other *Pelargonium* species and their hybrids is added to a wide range of food categories for flavouring purposes. Although individual consumption figures for the EU are not available, the Fenaroli's handbook of flavour ingredients (Burdock, 2009) cites values of 0.0005 mg/kg bw per day for geranium rose oil (FEMA 2508).

The majority 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 1, Section 1.2).

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 geranium rose oil are expected to be extensively metabolised and excreted in the target species.

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

No safety concern would be expected for the consumer from the use of geranium rose oil up to the maximum proposed use level in feed for the target animals.

3.3.3. Safety for the user

No specific data were provided by the applicant regarding the safety of the additive for users. The applicant produced a safety data sheet[31] for geranium rose oil where hazards for users have been identified.

The applicant provided some scientific publications retrieved from a literature search.[32] Only three papers were considered by the Panel. They provide some evidence regarding irritancy (Opdyke, 1979) and dermal sensitisation in exposed populations (Larsen et al., 2001; Lalko and Api, 2006).

The essential oil under assessment should be considered as irritant to skin and eyes, and as a skin and respiratory sensitiser.

3.3.4. Safety for the environment

P. graveolens originated in South Africa in a limited geographical area. Subsequently, following some 300 years of interest in its sensory properties, the true species and its numerous hybrids now

[31] Technical dossier/Supplementary Information May 2022/Annex_VII_SIn reply_geranium_rose_oil_MSDS. Hazards for eye irritation/eye damage (H318, category 1), skin 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).

[32] Technical dossier/Supplementary information May 2022/Literature search_geranium_rose_oil.

have a worldwide distribution (see Section 3.1). The use of geranium rose oil in animal feed under the proposed conditions of use is not expected to pose a risk to the environment.

3.4. Efficacy

P. graveolens and its preparations are listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by FEMA with the reference number 2508 (geranium rose oil).

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

4. Conclusions

Geranium rose oil from *Pelargonium graveolens* L'Hér. may be produced from plants of different geographical origins and by various processes resulting in preparations with different composition and toxicological profiles. Therefore, the following conclusions apply only to geranium rose oil produced by steam distillation of the herbaceous parts of *P. graveolens*.

The FEEDAP Panel concludes that geranium rose oil is safe up to the maximum proposed use levels in feed of 5 mg/kg complete feed for all animal species. The FEEDAP Panel considers that the use in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

No concerns for consumers were identified following the use of the geranium rose oil up to the maximum proposed use level in feed.

The essential oil under assessment should be considered as irritant to skin and eyes, and as a skin and respiratory sensitiser.

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

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

5. Documentation provided to EFSA/Chronology

Date	Event
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
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
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*
10/05/2022	Reception of supplementary information from the applicant (partial dataset: geranium rose oil) - Scientific assessment remains suspended

Date	Event
19/01/2023	The application was split and a new EFSA-Q-2023-00034 was assigned to the preparation included in the present assessment
23/01/2023	Scientific assessment re-started for the preparation included in the present assessment
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, lemongrass oil and clove oil
04/07/2023	Opinion adopted by the FEEDAP Panel on geranium rose oil (EFSA-Q-2023-00034). End of the Scientific assessment for the preparation included in the present assessment. The assessment of other preparations in BGD 07 is still ongoing

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Abbreviations

AFC	EFSA Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials
BDG	botanically defined group
bw	body weight
CAS	Chemical Abstracts Service
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CG	chemical group
CDG	chemically defined group
CoE	Council of Europe
DM	dry matter
EEIG	European economic interest grouping
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
FEMA	Flavour Extract Manufacturers Association
FFAC	Feed Flavourings authorisation Consortium of (FEFANA) the EU Association of Specialty Feed Ingredients and their Mixtures
FGE	Flavouring Group Evaluation
FLAVIS	the EU Flavour Information System
FL-No	FLAVIS number
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector

GC–MS	gas chromatography–mass spectrometry
ISO	International standard organisation
LOD	limit of detection
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
MOET	combined margin of exposure (total)
MOE	margin of exposure
NOAEL	no observed adverse effect level
OECD	Organization for Economic Co-operation and Development
QSAR	Quantitative Structure–Activity Relationship
TTC	threshold of toxicological concern
UF	uncertainty factor
WHO	World Health Organization