

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1419**of 22 August 2022****concerning the authorisation of buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Buchu leaves oil was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of an essential oil from the leaves of *Agathosma betulina* (P.J. Bergius) Pillans (buchu leaf essential oil) for all animal species.
- (4) The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The applicant requested the additive to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans in water for drinking should not be allowed.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2022 ⁽³⁾ that, under the proposed conditions of use, buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans does not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans should be considered as an irritant to skin and eyes, and as a dermal and respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (7) The Authority further concluded, that buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans is recognised to flavour food and its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2022;20(3):7160.

- (8) The assessment of buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.
- (9) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (10) The fact that buchu leaf essential oil from *Agathosma betulina* (P.J. Bergius) Pillans is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.
- (11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 12 March 2023 in accordance with the rules applicable before 12 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 12 September 2023 in accordance with the rules applicable before 12 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 12 September 2024 in accordance with the rules applicable before 12 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg additive/kg of complete feed with a moisture content of 12 %			

Category: Sensory additives. Functional group: Flavouring compounds

2b85c-eo	Buchu leaf essential oil	Additive composition	All animal species except cats	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. Mixture with other additives containing methyleugenol is not permitted. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — chickens for fattening and other minor poultry species for fattening: 0,1 mg; — laying hens and other minor poultry species for laying and breeding purposes, turkeys for fattening and rabbits: 0,15 mg; — piglets of all <i>Suidae</i> species: 0,20 mg; — all <i>Suidae</i> for fattening: 0,25 mg; — sows and dairy ruminants: 0,30 mg;	12.9.2032
		Buchu leaf essential oil obtained from the leaves of <i>Agathosma betulina</i> (P.J. Bergius) Pillans Liquid form Methyleugenol ≤ 0,17 % <i>Characterisation of the active substance</i> Buchu leaf essential oil produced by steam distillation from the leaves of <i>Agathosma betulina</i> (P.J. Bergius) Pillans as defined by the Council of Europe ⁽¹⁾ . d,l-Isomenthone: 19–27 % d-Limonene: 19–26 % 2-Hydroxypiperitone (or diosphenol): 8–17 % p-Menthan-3-one: 5–12 % Pulegone: 1,5–8 % CAS number: 68650-46-4 CoE number: 85c FEMA number: 2169	Cats	-	-	0,2		

		<i>Analytical method</i> ⁽²⁾ For the determination of d-limonene and d,l-isomenthone (phytochemical markers) in the feed additive (buchu leave essential oil): — gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 11024)					— ruminants for fattening and horses: 0,45 mg; — calves (milk replacer), dogs, fish and ornamental fish: 0,5 mg; — other species, except cats: 0,1 mg.' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 4. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	
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⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en