



2025/279

13.2.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/279

of 12 February 2025

concerning the authorisation of cajeput essential oil from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. 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) The substance cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. This substance was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1), point (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 authorisation of cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. as a feed additive for all animal species, requesting the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant requested the additive to be authorised for use also 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 this additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 March 2024 ⁽³⁾ that cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. is safe for all animal species at certain maximum concentrations further specified for each species. Furthermore, it concluded that no concerns for consumers were identified following the use of cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L., under the proposed conditions, and that its use is not expected to pose a risk to the environment under the proposed conditions. The Authority concluded that cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. should be considered as an irritant to skin and eyes, and as a dermal and respiratory sensitiser. The Authority further concluded that since cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. 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. It also verified the report on the method 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ EFSA Journal. 2024;22(4):8732.

- (6) In view of the above, the Commission considers that cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) The Commission considers that safety reasons do not require the setting of maximum levels for cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L. In order to allow better control, the recommended maximum content should be indicated on the label of the feed additive. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.
- (8) 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 provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) 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 an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additive cajeput essential oil derived from *Melaleuca cajuputi* Maton & Sm. ex R. Powell and *Melaleuca leucadendra* (L.) L., as authorised pursuant to Directive 70/524/EEC and premixtures containing this additive, which are produced and labelled before 5 September 2025 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 March 2026 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before 5 March 2027 in accordance with the rules applicable before 5 March 2025 may continue to be placed on the market and used until the stocks concerned 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, 12 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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 of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b276-eo	Cajeput essential oil	<i>Additive composition</i> Essential oil from the leaves of <i>Melaleuca cajuputi</i> Maton & Sm. ex R. Powell and <i>Melaleuca leucadendra</i> (L.) L. Liquid form <i>Characterisation of active substance</i> Cajeput essential oil Essential oil as defined by the Council of Europe ⁽¹⁾ extracted by steam distillation from the leaves of <i>Melaleuca cajuputi</i> Maton & Sm. ex R. Powell and <i>Melaleuca leucadendra</i> (L.) L. CAS number: 8008-98-8 for essential oil from <i>Melaleuca leucandendron</i> L. Einecs number: 931-800-6 FEMA number: 2225 CoE number: 276 <i>Specifications</i> — 1,8-Cineole (eucalyptol): 50-70 % — α-Terpineol: 4-12 % — d-Limonene: 3-9 % — methyleugenol, estragole and safrole: $\leq 0,01$ mg/kg <i>Analytical method</i> ⁽²⁾ For the determination of 1,8-cineole (phytochemical marker) in the feed additive: — gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 11024)	All animal species	—	—	—	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 the stability to heat treatment shall be indicated. 3. 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 %: — 23 mg for turkeys for fattening; — 18 mg for chickens for fattening and minor poultry for fattening; — 18 mg for all poultry reared for laying or breeding; — 26 mg for all poultry for laying and breeding; — 18 mg for ornamental birds; — 37 mg for pigs for fattening; — 31 mg for pigs for fattening of minor <i>Suidae</i>;	5 March 2035

Identification number of the feed 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 of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
							— 31 mg for piglets (suckling and weaned) of all <i>Suidae</i>; — 30 mg for all <i>Suidae</i> for reproduction; — 78 mg for calves for fattening up to 6 months; — 69 mg for sheep and goats; — 69 mg for cattle for fattening, other ruminants for fattening except sheep and goats, and <i>Camelidae</i> for fattening; — 45 mg for all other ruminants, and all other <i>Camelidae</i>; — 50 mg for <i>Equidae</i>; — 28 mg for rabbits; — 40 mg for salmonids and minor fin fish; — 30 mg for dogs; — 5 mg for cats; — 50 mg for ornamental fish; — 5 mg for other species and categories.' 4. 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 3.	

Identification number of the feed 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 of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
							5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	

(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