



2024/2464

13.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2464

of 12 September 2024

concerning the authorisation of pine white essential oil from *Pinus pinaster* Aiton 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 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 pine white essential oil from *Pinus pinaster* Aiton 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 belonging to the category 'sensory additives' and to the functional group 'flavouring compounds' 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 pine white essential oil from *Pinus pinaster* Aiton 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'. That 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 21 March 2023 ⁽³⁾ that pine white essential oil from *Pinus pinaster* Aiton is safe at certain maximum concentrations further specified for each species. Furthermore, it concluded that pine white essential oil from *Pinus pinaster* Aiton is safe for consumers and for the environment at the proposed use level in feed. It concluded that pine white essential oil from *Pinus pinaster* Aiton should be considered as irritant to skin and eyes, and as a skin and respiratory sensitiser. The Authority further concluded that since pine oleoresins and their preparations are recognised to flavour food and the function of pine white essential oil from *Pinus pinaster* Aiton in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. The Authority 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 2023;21(2):7952.

- (6) In view of the above, the Commission considers that pine white essential oil from *Pinus pinaster* Aiton satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. 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 contents for pine white essential oil from *Pinus pinaster* Aiton. In order to allow better control, the recommended maximum content should be indicated on the label of the feed additives. 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 pine white essential oil from *Pinus pinaster* Aiton, 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 pine white essential oil from *Pinus pinaster* Aiton as authorised pursuant to Directive 70/524/EEC and premixtures containing that additive, which are produced and labelled before 3 April 2025 in accordance with the rules applicable before 3 October 2024 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the additive referred to in paragraph 1, which are produced and labelled before 3 October 2025 in accordance with the rules applicable before 3 October 2024 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 3 October 2026 in accordance with the rules applicable before 3 October 2024 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 September 2024.

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 active substance/kg of complete feed with a moisture content of 12 %			

Category: Sensory additives. Functional group: Flavouring compounds

2b340-eo	Pine white essential oil	<i>Additive composition</i> Essential oil from the oleoresin of <i>Pinus pinaster</i> Aiton Liquid form <i>Characterisation of the active substance</i> Pine white essential oil Essential oil as defined by the Council of Europe ⁽¹⁾ obtained from oleoresin of <i>Pinus pinaster</i> Aiton by steam distillation followed by rectification of the oleoresin CAS number: 8002-09-3 FEMA number: 3089 CoE number: 340 Specifications: α-Pinene (pin-2(3)-ene) 70,85 % β-Pinene (pin-2(10)-ene) 11,20 % Longifolene 0.2–2,5 % β-Caryophyllene 0.3–3,0 % Camphene 0.6–1,5 % Myrcene 0.4–1,5 % <i>Analytical method</i> ⁽²⁾ For the determination of the phytochemical markers pin-2(3)-ene and pin-2(10)-ene in the feed additive (pine white essential oil) — gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 11020).	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. - 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%: — 35 mg for all poultry for laying or breeding purposes; — 25 mg for all poultry species reared for laying and breeding except turkeys reared for breeding; — 33 mg for turkeys for fattening and reared for breeding; — 25 mg for chickens for fattening and minor poultry for fattening; — 14 mg for ornamental birds; — 35 mg for all Suidae; — 50 mg for all ruminants, Camelidae and Equidae; — 35 mg for salmonids and minor finfish;	3 October 2034
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							— 50 mg for ornamental fish; — 35 mg for rabbits; — 50 mg for dogs; — 20 mg for cats; — 20 mg for other animal species or 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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 breathing, eye and skin protective equipment.	
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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.