



2024/2414

16.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2414

of 13 September 2024

concerning the authorisation of juniper essential oil and juniper tincture from *Juniperus communis* L. as feed additives 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 substances juniper essential oil and juniper tincture from *Juniperus communis* L. were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of Feed Additives as existing products 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 juniper essential oil and juniper tincture from *Juniperus communis* L. as feed additives for all animal species, requesting the additives 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 additives 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 these additives in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 22 March 2023 ⁽³⁾ that, under the proposed conditions of use, juniper tincture from *Juniperus communis* L. is safe for all animal species and consumers. The Authority also concluded that juniper essential oil from *Juniperus communis* L. is safe for all animal species and consumers at certain maximum concentrations further specified for each species. It also found that the use of juniper oil and juniper tincture from *Juniperus communis* L. in animal feed, under the proposed conditions, is not expected to pose a risk to the environment. It concluded that juniper essential oil and juniper tincture from *Juniperus communis* L. should be considered as irritants to skin and eyes, and as skin and respiratory sensitisers. The Authority further concluded that since the berries of *Juniperus communis* L. and their preparations 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. The Authority also verified the report on the method of analysis of the feed additives 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(4):7977.

- (6) In view of the above, the Commission considers that juniper essential oil and juniper tincture from *Juniperus communis* L. satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those substances 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 juniper essential oil and juniper tincture from *Juniperus communis* L. 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 juniper essential oil and juniper tincture from *Juniperus communis* L., 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 substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additives juniper essential oil and juniper tincture from *Juniperus communis* L. as authorised pursuant to Directive 70/524/EEC and premixtures containing those additives, which are produced and labelled before 6 April 2025 in accordance with the rules applicable before 6 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 feed additives referred to in paragraph 1, which are produced and labelled before 6 October 2025 in accordance with the rules applicable before 6 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 additives referred to in paragraph 1, which are produced and labelled before 6 October 2026 in accordance with the rules applicable before 6 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, 13 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b249-eo	Juniper essential oil	<p><i>Additive composition</i></p> <p>Essential oil from the berries of <i>Juniperus communis</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Juniper essential oil</p> <p>Essential oil as defined by the Council of Europe ⁽¹⁾obtained from the berries of <i>Juniperus communis</i> L. by steam distillation and further condensation of volatile constituents and separation from the aqueous phase by decantation.</p> <p>CAS number: 8002-68-4 FEMA number: 2604 CoE number: 249</p> <p><i>Specifications</i></p> <p>α-Pinene (pin-2(3)-ene): 25,45 % β-Pinene (pin-2(10)-ene): 1,12 % Sabinene (4(10)-thujene): 4,20 % Myrcene: maximum 3,22 %.</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the determination of the phytochemical marker pin-2(3)-ene in the feed additive (juniper essential oil): gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 8897).</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 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 %: — 5 mg for all poultry for laying or breeding purposes; — 4 mg for all poultry reared for laying or breeding except turkeys reared for breeding; — 4 mg for chickens for fattening and minor poultry for fattening; 	6.10.2034

							<ul style="list-style-type: none"> — 5 mg for turkeys for fattening, and turkeys reared for breeding; — 3 mg for ornamental birds; — 10 mg for all Suidae for reproduction; — 7 mg for piglets (suckling and weaned) of all Suidae; — 8 mg for pigs for fattening; — 7 mg for pigs for fattening of minor Suidae; — 15 mg for: <ul style="list-style-type: none"> — sheep and goats; — ruminants and Camelidae for fattening; — 10 mg for all other ruminants and Camelidae; — 15 mg for Equidae; — 17 mg for salmonids and minor fin fish; — 20 mg for ornamental fish; — 6 mg for rabbits; — 18 mg for dogs; — 3 mg for cats; — 3 mg for other animal species and categories'.
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							<p>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.</p> <p>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.</p>	
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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

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b249-t	Juniper tincture	<p><i>Additive composition</i></p> <p>Tincture from the berries of <i>Juniperus communis</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Juniper tincture</p> <p>Tincture as defined by the Council of Europe ⁽¹⁾ obtained from the berries of <i>Juniperus communis</i> L. by extraction with a water/ethanol solvent mixture, pressing and filtration.</p> <p>CoE number: 249</p> <p><i>Specifications</i></p> <p>Dry matter: maximum 1,5 % Tannins (as pyrogallol): maximum 0,02 % α-Pinene: maximum 0,0064 %</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For the determination of the phytochemical marker tannins in the feed additive (juniper tincture): spectrophotometry (European Pharmacopoeia monograph 20814).</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 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 content of the active substance per kg of complete feedingstuff, with a moisture content of 12 %: 45 mg for all animal species.' 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. 	6.10.2034

								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