



2024/1068

15.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1068

of 12 April 2024

concerning the authorisation of a preparation of rosemary extract as a feed additive for cats and dogs

(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of rosemary extract obtained from dried leaves of *Rosmarinus officinalis* L., by acetone or ethanol extraction. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of rosemary extract as a feed additive for cats and dogs, requesting that additive to be classified in the category 'technological additives' and in the functional group 'antioxidants'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 November 2021 ⁽²⁾ that, under the proposed conditions of use, the preparation of rosemary extract obtained from dried leaves of *Rosmarinus officinalis* L., by acetone or ethanol extraction, is safe up to the maximum use levels of 300 mg/kg and 50 mg/kg complete feed for dogs and cats, respectively (that corresponds to a concentration of carnolic acid of 34 and 5 mg/kg respectively). It also concluded that the preparation should be considered as irritant to skin and eyes, but it could not conclude on its potential to be skin sensitiser. It considered that exposure through inhalation is unlikely. Since rosemary extract is used as a food additive, and its function in feed would be essentially the same as that in food, the Authority concluded that 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.
- (5) In view of the above, the Commission considers that the preparation of rosemary extract satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation 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.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2022;20(1):6978.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'antioxidants', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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 carnosic acid/kg of complete feed with a moisture content of 12 %			
Category: technological additives. Functional group: antioxidants								
1b392	Rosemary extract	<p><i>Additive composition</i></p> <p>Preparation of rosemary extract from dried leaves of <i>Rosmarinus officinalis</i> with carnosic acid 9-12 %, sum of carnosic acid and carnosol ≥ 10 %</p> <p>Liquid form</p> <p>Extract is obtained through acetone or ethanol extraction methods.</p> <p>Residual solvents (acetone or ethanol) ≤ 250 mg/kg Camphor ≤ 150 mg/kg</p> <p><i>Characterisation of the active substances</i></p> <p>Carnosic acid C₂₀H₂₈O₄ CAS number 3650-09-7</p> <p>Carnosol C₂₀H₂₆O₄ CAS number 5957-80-2</p> <p>Sum of carnosic acid and carnosol in the extract: ≥ 90 % w/w of the total phenolic diterpenes of the extract; ≥ 15 % w/w of total volatiles</p>	Cats Dogs			5 34	<ol style="list-style-type: none">1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.2. The simultaneous use of different sources of carnosic acid shall not result in exceeding the permitted maximum level of that substance in complete feedingstuffs established for each relevant species.3. 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.	5 May 2034

		<p><i>Analytical method ⁽¹⁾</i></p> <p>For the quantification of carnosic acid and carnosol in the feed additive:</p> <ul style="list-style-type: none">— High performance liquid chromatography with spectrophotometric detection (HPLC-UV) <p>For the quantification of carnosic acid in compound feed:</p> <ul style="list-style-type: none">— Gas chromatography with flame ionisation detection (GC-FID)						
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⁽¹⁾ 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