

COMMISSION IMPLEMENTING REGULATION (EU) 2019/913**of 29 May 2019****concerning the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats and repealing Regulation (EC) No 163/2008 (holder of authorisation Bayer HealthCare AG)****(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 and renewing such authorisation.
- (2) Lanthanum carbonate octahydrate was authorised for 10 years as a feed additive for cats by Commission Regulation (EC) No 163/2008 ⁽²⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 November 2018 ⁽³⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.
- (5) The assessment of lanthanum carbonate octahydrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 163/2008 should be repealed.
- (7) 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

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 163/2008 is repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Regulation (EC) No 163/2008 of 22 February 2008 concerning an authorisation of the preparation Lanthanum carbonate octahydrate (Lantharenol) as a feed additive (OJ L 50, 23.2.2008, p. 3).⁽³⁾ EFSA Journal 2018;16(12):5542.

Article 3

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, 29 May 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	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 of zootechnical additives. Functional group: other zootechnical additives (decrease in phosphorous excretion via urine)

4d1	Bayer HealthCare AG	Lanthanum carbonate octahydrate	<p><i>Additive composition:</i> Preparation of Lanthanum carbonate octahydrate At least 85 % Lanthanum carbonate octahydrate as active substance.</p> <p><i>Characterisation of the active substance:</i> Lanthanum carbonate octahydrate $\text{La}_2(\text{CO}_3)_3 \cdot 8\text{H}_2\text{O}$ CAS number 6487-39-4</p> <p><i>Analytical method</i> ⁽¹⁾ For the quantification of Carbonate in the feed additive: Community Method (Reg. (EC) No 152/2009 – Annex III-O) For the quantification of Lanthanum in the feed additive and feedingstuffs: Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES)</p>	Cats	1 500	7 500	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. 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 breathing protection. In the directions for use of the additive, the following shall be indicated: 'avoid simultaneous use of feeds with high level of phosphorus.' 	25 June 2029
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>