



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/2281152/2024 CIS
(POOL/G5/2024/2281152/2281152-EN
CIS.docx)
[...](2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of lanthanum carbonate octahydrate as a feed additive for
dogs (holder of authorisation: Porus GmbH)**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of lanthanum carbonate octahydrate as a feed additive for dogs (holder of authorisation: Porus GmbH)

(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 nutrition¹, 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 lanthanum carbonate octahydrate as a feed additive. 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 lanthanum carbonate octahydrate as a feed additive for dogs, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘other zootechnical additives’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 13 March 2024² that, under the proposed conditions of use, lanthanum carbonate octahydrate is safe for adult dogs at the maximum recommended level of 7500 mg/kg complete feed. It also concluded that lanthanum carbonate octahydrate is not irritant to skin or eyes, is not a skin sensitiser and exposure by inhalation is considered to be unlikely. The Authority further concluded that lanthanum carbonate octahydrate is efficacious in the reduction of phosphorus bioavailability in adult dogs at the minimum inclusion level of 1500 mg/kg complete feed. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment of the same substance for its use in cats, regarding the methods used for the control of the lanthanum carbonate octahydrate in animal feed, are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission

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

² EFSA Journal. 2024;22:e8729.

Regulation (EC) No 378/2005³, an evaluation report of the Reference Laboratory is therefore not required.

- (6) In view of the above, the Commission considers that lanthanum carbonate octahydrate 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 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 ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
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,

For the Commission
The President
Ursula VON DER LEYEN

³ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).