

# Safety and efficacy of a feed additive consisting of lanthanum carbonate octahydrate for dogs (Porus GmbH)

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## Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of lanthanum carbonate octahydrate as a zootechnical feed additive for dogs. The additive is already authorised for use in feed for cats. The FEEDAP Panel concluded that the additive lanthanum carbonate octahydrate is safe for adult dogs at the maximum recommended level of 7500 mg/kg complete feed. The additive is not irritant to skin or eyes, is not a skin sensitiser and exposure by inhalation is considered to be unlikely. The Panel also 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.

## KEYWORDS

dogs, efficacy, lanthanum carbonate octahydrate, other zootechnical additives, safety, zootechnical additives

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## 1 | INTRODUCTION

### 1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Porus GmbH<sup>2</sup> for the authorisation of the additive consisting of lanthanum carbonate octahydrate, when used as a feed additive for dogs (category: zootechnical additives; functional group: other zootechnical additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The dossier was received on 28 June 2023 and the general information and supporting documentation are available at <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00440>. The particulars and documents in support of the application were considered valid by EFSA as of 2 October 2023.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals and the user and on the efficacy of the feed additive consisting of lanthanum carbonate octahydrate, when used under the proposed conditions of use (see Section 3.1).

### 1.2 | Additional information

The additive under assessment consists of lanthanum carbonate octahydrate. EFSA issued one opinion on the safety and efficacy of the same additive when used in feed for cats (EFSA FEEDAP Panel, 2022), and three other opinions on the same additive consisting of lanthanum carbonate octahydrate from a different applicant for cats and dogs (EFSA, 2007; EFSA FEEDAP Panel, 2012, 2019).

The additive consisting of lanthanum carbonate octahydrate is currently authorised for use in feed for cats (4d23).<sup>3</sup> Another additive consisting of lanthanum carbonate octahydrate is also authorised for use in cats and was also authorised for use in dogs until 2022, the holder of the authorisation being different from the current applicant (4d1).<sup>4</sup>

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier<sup>5</sup> in support of the authorisation request for the use of lanthanum carbonate octahydrate as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 3 October 2023 to 3 January 2024; the comments received were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002<sup>6</sup> and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,<sup>7</sup> a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 19 January 2024 to 9 February 2024 for which no comments were received.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

<sup>1</sup>Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

<sup>2</sup>Porus GmbH, Alfred-Nobel Strasse 10, 40789, Monheim, Germany.

<sup>3</sup>Commission implementing regulation (EU) 2022/1471 of 5 September 2022 concerning the authorisation of lanthanum carbonate octahydrate as a feed additive for cats (holder of authorisation Porus GmbH).

<sup>4</sup>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).

<sup>5</sup>Dossier reference: FEED-2023-15311.

<sup>6</sup>Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

<sup>7</sup>Decision <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the lanthanum carbonate octahydrate in animal feed are valid and applicable for the current application.<sup>8</sup>

## 2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lanthanum carbonate octahydrate is in line with the principles laid down in Regulation (EC) No 429/2008<sup>9</sup> and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on studies concerning the safety of use of the additive for users (EFSA FEEDAP Panel, 2023).

## 3 | ASSESSMENT

The additive lanthanum carbonate octahydrate is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in feed for adult dogs to reduce phosphorus bioavailability.

### 3.1 | Characterisation

The additive is specified to contain at least 85% lanthanum carbonate octahydrate as the active substance, the remaining being free water. Lanthanum carbonate octahydrate has the Chemical Abstracts Service (CAS) number 6487-39-4, molecular formula  $\text{La}_2(\text{CO}_3)_3 \cdot 8\text{H}_2\text{O}$  and a molecular weight of 601.9 g/mol.

The additive was fully characterised in the previous opinion for its use in cats (EFSA FEEDAP Panel, 2022). No new data have been submitted in the present application and the applicant does not propose changes in the composition/manufacturing. The data assessed in the previous opinion are fully applicable.

No data on the presence of small particles including nanoparticles were submitted for the product under assessment. However, considering that lanthanum carbonate is known to dissolve in the acidic environment of the stomach, it is expected that any potential nanoparticles present in the additive would also dissolve in the acidic gastric fluid. The Panel considers that a further characterisation of the potential presence of nanoparticles is not needed.

The additive is intended for use in feed for dogs at a proposed minimum concentration of 1500 mg/kg complete feed and a maximum use level of 7500 mg/kg complete feed via a complementary feed. The applicant recommends including under the other provisions of the authorisation: (i) The additive should be used in adult dogs, (ii) recommended level of inclusion in moist feed with 20%–25% dry matter content of 340–2100 mg per kg and (iii) to avoid the simultaneous use of feeds with high level of phosphorus.

### 3.2 | Safety

The additive is intended to be used only in feed for dogs, and therefore, there is no need to assess the safety for the consumers and the environment. To support the safety of the additive for the target species and the users, the applicant referred to the studies submitted in the context of a previous application for the same active substance and already assessed by the FEEDAP Panel (EFSA FEEDAP Panel, 2012).

#### 3.2.1 | Safety for the target species

The safety of lanthanum carbonate octahydrate for dogs was established in a previous opinion based on a tolerance study in which no adverse effects were observed after supplementing the dogs' diets with 10-fold the maximum use level (75,000 mg/kg complete feed) (EFSA FEEDAP Panel, 2012). The Panel notes that the composition and the conditions of use of the additive under assessment are the same as those previously assessed, and therefore, the conclusions reached in the previous opinion fully apply to the additive under assessment in the current application. The FEEDAP Panel also concluded that lanthanum carbonate does not pose a concern for genotoxicity (EFSA FEEDAP Panel, 2022).

<sup>8</sup>Evaluation report available on the EU Science Hub [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en) FAD-2020-0104.

<sup>9</sup>Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

The applicant performed one structured literature search to support the safety of the additive for dogs. Information was searched in three databases (PubMed, SEARCH and Google Scholar), covering the period 2011–2023. The search strategy (including keywords relevant to the active substance and safety for dogs), inclusion and exclusion criteria were provided.

A total of 40 articles were identified through the database searches from which seven publications were selected by the applicant as relevant. Of these, only one paper reported information considered relevant for the current assessment by the FEEDAP Panel (Damment, 2011). The rest of the papers were not considered to add new information for the current assessment of the safety for dogs as they refer to either the previous opinions of the FEEDAP Panel on the same active substance or did not specifically provide information on the safety of lanthanum carbonate octahydrate.

Damment (2011) reported the results of a series of studies in mice, rats and dogs, intended to assess the pharmacological safety of lanthanum carbonate. None of the studies in dogs indicated any adverse effects on cardiovascular and respiratory systems following a single intraduodenal dose of lanthanum carbonate of up to 2000 mg/kg body weight, or on the neurobehaviour of dogs following a 52-week treatment with oral doses of lanthanum carbonate up to 2000 mg/kg body weight.

#### 3.2.1.1 | *Conclusions on safety for the target species*

Considering that the additive is not genotoxic, that the tolerance study already assessed in a previous opinion showed that dogs can tolerate up to 10-fold the maximum proposed use level without adverse effects and that no new evidence has been found in the literature that would question the previous assessments, the FEEDAP Panel concludes that the additive lanthanum carbonate octahydrate is safe for adult dogs at the maximum recommended level of 7500 mg/kg complete feed.

#### 3.2.2 | Safety for the user

The safety for the user was already assessed in the previous opinion for the use of the additive in cats (EFSA FEEDAP Panel, 2022). In that opinion, the Panel concluded that the additive is not irritant to skin or eyes, is not a skin sensitiser and that exposure by inhalation is considered to be unlikely. The Panel considers that the new use in dogs would not introduce concerns not already considered in the previous opinion, and therefore, reiterates its previous conclusion that the handling of the additive is safe for users.

### 3.3 | Efficacy

To support the efficacy of the additive as a phosphate binder in adult dogs, the applicant referred to the efficacy studies submitted in a previous application for the same additive and already assessed by the FEEDAP Panel (EFSA FEEDAP Panel, 2012). In that opinion, the FEEDAP Panel noted that (i) the efficacy of the additive in reducing phosphorus absorption was demonstrated in cats, (ii) positive effects in reducing phosphorus urinary excretion were observed in one study in dogs and (iii) the mode of action of the additive can be reasonably assumed to be comparable in dogs and cats. Therefore, the Panel concluded that lanthanum carbonate octahydrate has the potential to reduce phosphorus bioavailability in adult dogs at the lowest recommended level of 1500 mg/kg complete feed. The Panel notes that the composition and the conditions of use of the additive under assessment are the same as the one previously assessed. Therefore, the conclusions reached in the previous assessment fully apply to the current application.

### 3.4 | Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation<sup>10</sup> and good manufacturing practice.

## 4 | CONCLUSIONS

The additive lanthanum carbonate octahydrate is safe for adult dogs at the maximum recommended level of 7500 mg/kg complete feed.

The additive is not irritant to skin or eyes, is not a skin sensitiser and exposure by inhalation is considered to be unlikely.

The Panel also concludes that lanthanum carbonate octahydrate is efficacious in reducing phosphorus bioavailability in adult dogs at the minimum inclusion level of 1500 mg/kg complete feed.

### ABBREVIATIONS

CAS                      Chemical Abstracts Service

<sup>10</sup>Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

EURL European Union Reference Laboratory  
FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed

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## CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact [interestmanagement@efsa.europa.eu](mailto:interestmanagement@efsa.europa.eu).

## REQUESTOR

European Commission

## QUESTION NUMBER

EFSA-Q-2023-00440

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