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Safety and efficacy of a feed additive consisting of lanthanum carbonate octahydrate (Lanthan One) for cats (Porus GmbH)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Gabriele Aquilina, Montserrat Anguita, Jordi Tarrés-Call, Maria Vittoria Vettori and Jaume Galobart

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 (Lanthan One) as a zootechnical feed additive for cats. The FEEDAP Panel concluded that lanthanum carbonate octahydrate is safe for cats at the maximum proposed use level of 7,500 mg/kg complete feed. The additive is not irritant to skin or eyes, is not a skin sensitiser and exposure of users by inhalation is considered unlikely. The Panel also concluded that the additive is efficacious as a phosphate binder in adult cats at the minimum proposed conditions of use (1,500 mg/kg complete feedingstuffs).

Keywords: zootechnical additives, other zootechnical additives, cats, safety, efficacy, lanthanum carbonate octahydrate, Lanthan One

Requestor: European Commission

Question number: EFSA-Q-2020-00848

Correspondence: feedap@efsa.europa.eu

Panel members: Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] 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[2] for the authorisation of the additive consisting of lanthanum carbonate octahydrate (Lanthan One), when used as a feed additive for cats (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). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 31 March 2021.

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 (Lanthan One), when used under the proposed conditions of use (see Section 3.1.5).

1.2. Additional information

EFSA issued two opinions on the safety and efficacy of an additive consisting of lanthanum carbonate octahydrate (Lantharenol®) from a different applicant, one for cats (EFSA, 2007) and one for dogs (EFSA FEEDAP Panel, 2012a), and another one on the renewal of the authorisation of the same additive for cats (EFSA FEEDAP Panel, 2019).

An additive consisting of lanthanum carbonate octahydrate is currently authorised for use in feed for cats and dogs (4d1)[3] being the holder of the authorisation different from the current applicant.

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[4] in support of the authorisation request for the use of lanthanum carbonate octahydrate (Lanthan One) as a feed additive for cats.

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.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the lanthanum carbonate octahydrate in animal feed. The Executive Summary of the EURL report can be found in Annex A.[5]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lanthanum carbonate octahydrate (Lanthan One) is in line with the principles laid down in Regulation

[1] 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.
[2] Porus GmbH, Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.
[3] 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) OJ L 146, 5.6.2019, p. 57. COMMISSION IMPLEMENTING REGULATION (EU) No 842/2012 of 18 September 2012 concerning the authorisation of a preparation of lanthanum carbonate octahydrate as a feed additive for dogs (holder of authorisation Bayer Animal Health GmbH) OJ L 252, 19.9.2012, p. 21.
[4] FEED dossier reference: FAD-2020-0104.
[5] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/finrep-fad-2020-0104-lanthanum-carbonate.pdf

(EC) No 429/2008[6] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), 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) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive lanthanum carbonate octahydrate (trade name: Lanthan One) is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in feed for cats as a phosphate binder.

3.1. Characterisation

3.1.1. Characterisation of the additive

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 $La_2(CO_3)_3 \cdot 8H_2O$ and a molecular weight of 601.9 g/mol.

Analytical data to confirm the specifications were provided for five batches of the additive, showing an average content of 88.6% lanthanum carbonate octahydrate (range: 86–93%) and 11.8% free water (range: 7–15%).[7] The applicant provided also specifications[8] for lanthanum 43–49%, carbonate 27–33% and residue on ignition of 44–58%, which were confirmed in the same batches.

The applicant set specifications for heavy metals (Pb and Cd: $\leq$ 1 mg/kg, Hg $\leq$ 0.2 mg/kg), As ($\leq$ 2 mg/kg), Cr ($\leq$ 2 mg/kg), Na ($\leq$ 500 mg/kg) and F ($\leq$ 100 mg/kg). The analysis of the same five batches used for the batch to batch variation showed compliance with these specifications (Pb, As and Cr < 0.5 mg/kg, Cd < 0.2 mg/kg, Hg < 0.05 mg/kg, F < 20 mg/kg and Na 5–26 mg/kg).[9]

Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) were analysed in three batches and found below the corresponding limit of quantification. The upper bound calculated as World Health Organization (WHO) Toxic Equivalent (TEQ) were 0.144 ng/kg for PCDD/Fs and 0.186 for PCBs. The sum of 6 International Council for the Exploration of the Sea (ICES)-PCB (28, 52, 101, 153, 138 and 180) was 2.05 μg/kg.[10]

Although, considering the manufacturing process, microbial contamination is not expected, specifications are set for total aerobic counts ($\leq 1 \times 10^4$ colony forming units (CFU)/g), yeast and moulds ($\leq$ 100 CFU/g), Enterobacteriaceae and *Escherichia coli* (absent in 1 g). Compliance with the specifications was confirmed in five batches.[7]

The results regarding impurities do not raise safety concerns.

3.1.2. Physical properties of the additive

The additive appears as a white to off-white powder with a density (five batches) ranging from 230 to 400 kg/m^3.[11] It is practically insoluble in water.

The dusting potential of three batches of the additive was determined using the DIN 55992-1 method and showed values on average of 22.4 mg/m^3 (range 17.2–27.8 mg/m^3).[12] The particle size distribution was analysed by laser diffraction in the same three batches; the results showed that virtually all particles have a diameter below 100 μm, about 90% below 50 μm and 9% below 10 μm.

[6] 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.
[7] Technical dossier/Section II/Annex II_1.
[8] Technical dossier/Section II/Annex II_2.
[9] Technical dossier/Section II/Annex II_1 and Supplementary information July 2021/Annex 1. The values reported in the brackets with the symbol < correspond to the reporting limits, being the limits of quantification (in mg/kg) 0.06 for Hg, 0.2 for Pb, 0.3 for Cd, As and Cr, and 20 for F.
[10] Technical dossier/Section II/Annex II_3.
[11] Technical dossier/Section II/Annex II_6.
[12] Technical dossier/Section II/Annex II_5 and Annex II_7.

3.1.3. Manufacturing process

[redacted]

3.1.4. Stability and homogeneity

The shelf life of the additive was studied in two batches when stored at 30°C and 65% relative humidity (RH) or at 40°C/75% RH for 21 months and in five further batches under the same conditions for 6 months. No losses of the active substance were observed at the end of the storage period.[14]

The additive is not intended to be incorporated to complete feed, but to be added to the final feed for cats in the form of a complementary feed. Therefore, no data was provided for the stability in feedingstuffs.

The capacity of the additive to be homogeneously distributed into a complementary feed was assessed by analysing 10 subsamples of the complementary feed (composition not given).[15] The coefficient of variation was 1.8%.

3.1.5. Conditions of use

The additive is intended for use in feed for cats at a proposed minimum concentration of 1,500 mg/kg complete feed and a maximum use level of 7,500 mg/kg complete feed via a complementary feed. The applicant recommends to include under the other provisions of the authorisation: (i) the additive should be used in adult cats; (ii) a recommended dose of inclusion in moist feed with 20-25% dry matter content of 340 to 2,100 mg per kg; and (iii) to avoid the simultaneous use of feeds with high level of phosphorus.

3.2. Safety

To support the safety of the additive for the target species and the users, the applicant made reference to the studies submitted in the context of a previous application for the same active substance and already assessed by the FEEDAP Panel (EFSA, 2007). The Panel notes that the composition and the conditions of use of the additive under assessment are the same as the one previously assessed and currently authorised, and therefore, the studies assessed in the previous opinion can be used to support the safety in the present evaluation. In addition, the applicant submitted published studies on the genotoxic potential of lanthanum-containing products and performed two literature searches.

3.2.1. Literature searches

The applicant performed two extensive literature searches to support the safety of the additive for cats and users. The first literature search, limited to the period 2017-April 2020, was complemented by the second search covering the period 2007–2021.[16] The first search was done in four databases (Scopus, Web of Science, PubMed and OVID) and Google Scholar. The second search comprised an automated database search (including several cumulative databases such as LIVIVO, NCBI, OVID, Toxinfo and individual databases) and a manual search using LIVIVO and Google Scholar. In both cases the search strategy (including keywords relevant to the active substance and safety for cats and humans), inclusion and exclusion criteria were provided.

A total of 182 papers were identified through the database searches from which 44 papers were selected. Most of the papers related to the use of lanthanum carbonate in human medicine, and only 11 papers provided information on studies in cats. None of these papers were considered to add new information for the current assessment of the safety for cats as they refer to either the previous opinions of the FEEDAP Panel on the same active substance, reported the same studies already considered in the 2007 opinion, involved non-healthy cats or were of short duration.

[13] Technical dossier/Section II/Annex II_8.
[14] Technical dossier/Section II/Annex II_9.
[15] Technical dossier/Section II/Annex II_10.
[16] Technical dossier/Section II/Annex III_2 and Supplementary information July 2021/Annex II.

Similarly, no papers were identified that provided relevant information on the safety of the product for users, with the exception of an accidental inhalation of lanthanum carbonate granules (see Section 3.2.4).

3.2.2. Toxicological studies

The genotoxic potential of lanthanum carbonate octahydrate as well as its toxicity to rats was assessed in a previous opinion by the FEEDAP Panel (EFSA, 2007), based on a bacterial reverse mutation assay, a chromosome aberration assay and a 90-day subchronic oral toxicity study in rats. Based on these studies, the FEEDAP Panel concluded that the additive was not genotoxic and did not show any evidence of systemic effects in the 90-day toxicity study.

The applicant provided additional evidence regarding the assessment of genotoxicity of lanthanum compounds in the form of two published papers (Damment et al., 2005; Han et al., 2021).

The paper by Damment et al. (2005) reports the results obtained in a series of *in vitro* and *in vivo* studies performed with lanthanum carbonate or lanthanum chloride, which are considered relevant for the current assessment and are summarised below.

An Ames test was performed to assess the potential of lanthanum carbonate to induce gene mutations in bacteria. The study was conducted in compliance with published recommendations using *Salmonella* Typhimurium strains TA98, TA100, TA1535, TA1537, TA1538, TA102 as well as in *E. coli* WP2uvrA and WP2uvrA (pkm101) strains. Five concentrations were tested up to 5,000 μg/plate in the absence and presence of metabolic activation. No biologically relevant increase in the number of revertant colonies was observed in any strain and experimental condition.

An *in vitro* gene mutation test at the *hprt* locus was conducted in Chinese Hamster Ovary (CHO) cells following OECD TG 476 (1997) and applying four concentrations of lanthanum carbonate up to 5,000 μg/ml both in the absence and presence of metabolic activation. No statistically significant changes in the frequency of mutations were induced by the test item in the absence and presence of metabolic activation.

An *in vitro* chromosomal aberration test was carried out according to recommendations of the United Kingdom Environmental Mutagen Society Guideline Committee to evaluate the potential of lanthanum carbonate to induce structural aberrations. The test item was applied up to 5,000 μg/ml in a short treatment in the presence of metabolic activation (3 h + 21 h of recovery) and up to 550 μg/ml in a continuous treatment without metabolic activation (24 h + 0 h recovery). CHO cells were harvested after 24 and 48 h of culturing. Statistically significant increases in chromosomal aberrations were observed; however they were not concentration-related, and the values were within the historical negative control range. Moreover, these significant increases were observed in association with high cytotoxicity (almost 50% reduction of the mitotic index compared to the negative controls) and considerable precipitation of the test item. Therefore, caution was posed in the assessment of these equivocal results.

An *in vivo* UDS assay was performed in Han Wistar rats to evaluate the potential of lanthanum chloride to induce DNA repair. The study was conducted according to OECD TG 486 (1997). Rats were treated intravenously for 28 days at 0.025, 0.05 and 0.1 mg/kg body weight (bw) per day. No changes in the nuclear grain count were induced by treatment with lanthanum chloride. Based on the EFSA's Scientific Committee opinion on 'Clarification of some aspects related to genotoxicity assessment' (EFSA Scientific Committee, 2017) negative UDS results cannot be considered supportive of lack of genotoxicity; therefore, this study was not further considered for the assessment of the additive.

An *in vivo* micronucleus test in bone marrow erythrocytes from CD-1 mice was performed according to OECD TG 474 (1997) to evaluate the potential of lanthanum carbonate to induce numerical and structural aberrations. Male and female mice were treated by gavage with a single administration of lanthanum carbonate at 800, 1,250 and 2,000 mg/kg bw. The highest dose corresponded to the top dose level recommended by OECD TG 474 (1997) for not toxic compounds. Mice were killed 24, 48 and 72 h after dosing. Changes in the ratio of polychromatic erythrocytes (PCE) to normochromatic erythrocytes (NCE) (PCE/NCE), observed in males after treatment with 2,000 mg/kg bw at 48 h and in females at low and mid dose at 72 h, suggested bone marrow exposure. Statistically significant dose-dependent increase in the frequency of micronuclei was observed in males at 48 h. However, the increased values were within the historical negative control range and significance could be attributed mainly to the low frequency of micronuclei detected in the controls, approaching to zero. Therefore, the increases were not considered biologically relevant.

An *in vivo* micronucleus test in bone marrow erythrocytes from Sprague–Dawley rats was conducted to evaluate the potential of lanthanum chloride to induce chromosome damage. Mice were

treated by a single intravenous administration at 0.025, 0.05 and 0.1 mg/kg bw. Animals were killed 24 or 48 h after dosing. The top dose was selected as the maximum associated with linear pharmacokinetics in previous experiments. Higher doses were not tested because considered not representative of the human exposure to lanthanum carbonate in clinical use. Plasma analysis supported bioavailability of the test item; the mean peak plasma lanthanum concentration detected after treatment with the top dose was approximately 2,000 ng/ml. No increase in the frequency of micronuclei was observed at any dose level.

The applicant provided also a recent study by Han et al. (2021) reporting an *in vivo* rodent alkaline comet assay performed with lanthanum nitrate in C57-ras transgenic mice and wild type animals following OECD TG 489 (2016). Mice were treated by oral gavage for 180 days (26 weeks) with 12.5, 25 and 50 mg lanthanum nitrate/kg bw. The analysis of DNA damage, performed within 6 h after last administration, was carried out in blood at 1, 28 and 180 days of exposure and in liver after 28 and 180 days of exposure. No changes in the percentage of tail DNA and tail length were observed in both tissues at harvest times, while the positive control induced a statistically significant increase of DNA damage. In order to evaluate the accumulation of lanthanum nitrate in tissues, the concentration of lanthanum was determined by inductively coupled plasma mass spectrometry in blood after 28 day-exposure and in liver, spleen and femur after 180 days of exposure. The results showed that lanthanum accumulated in tissues and organs, and the levels were significantly higher in liver compared to the other tissues. Concurrent histopathological examination of the liver indicated that no pathological damage was induced by the treatment. Overall, these data showed that lanthanum nitrate accumulated in tissues but did not induce DNA damage and toxic effects.

3.2.2.1. Conclusions on toxicology

Considering the complete genotoxicity package assessed, the Panel concludes that lanthanum carbonate does not raise a concern for the induction of gene mutations, structural and numerical chromosomal aberrations and therefore, confirms its previous conclusion that lanthanum carbonate does not pose a concern for genotoxicity. Moreover, lanthanum carbonate did not show any evidence of systemic effects in a 90-day toxicity study.

3.2.3. Safety for the target species

No studies on the safety of the additive for cats were submitted in the present application. Instead, the applicant made reference to the studies already assessed by the FEEDAP Panel in the context of a previous application for the authorisation of lanthanum carbonate octahydrate for cats (EFSA, 2007). The safety of lanthanum carbonate octahydrate for cats was established in that opinion based on two tolerance studies in healthy cats in which no adverse effects were seen after supplementing the cats' diets with 10-fold the maximum use level. The Panel notes that the composition and the conditions of use of the current additive are the same as the one previously assessed and currently authorised. Therefore, the conclusions reached in the previous assessment fully apply to the additive under assessment in the current application.

No studies were identified in the literature searches performed by the applicant (see section 3.2.1) that provided additional information on the safety of lanthanum carbonate octahydrate for cats.

3.2.3.1. Conclusions on safety for the target species

Considering that the additive is not genotoxic, that the tolerance studies already assessed in a previous opinion showed that cats can tolerate up to 10-fold the maximum use levels without adverse effects and that no new evidence has been found in the literature that would question the previous assessment, the FEEDAP Panel concludes that the additive lanthanum carbonate octahydrate is safe for cats at the maximum recommended level of 7,500 mg/kg complete feed.

3.2.4. Safety for the user

The safety of another lanthanum carbonate octahydrate for the user was previously assessed by the FEEDAP Panel (EFSA, 2007). Based on studies on skin and eye irritation, skin sensitisation, acute inhalation and dermal toxicity, the Panel concluded that 'Although the inhalation exposure did lead to some persistent effects in the lung of exposed rats which was not fully explained, the dusting studies indicate that user exposure via this route will not occur to any significant extent. The substance is not an irritant to skin or eye and is not a dermal sensitiser, is negative in genotoxicity tests and shows no evidence of systemic effects in a 90-day study. On the basis of all this information, there is no indication

for any specific protective measures for handling this product either in a domestic or commercial environment'. The Panel notes that the composition and physical properties of the current additive are the same as the one previously assessed and currently authorised, and therefore, considers that the conclusions reached in the previous opinion are applicable to the additive under assessment.

The additive under application has a low dusting potential (up to 28 mg/m^3), which indicates that exposure of users by this route would likely be low. In addition, the applicant stated that the product will not be commercialised as such but in the form of a granular complementary feed to be added on top of the complete feed for cats. No information on this complementary feed was provided.

No evidence was found in the literature searches performed (see Section 3.2.1) of adverse effects for users which could be associated to the intended use of the product. The only publication that described an adverse event was a case of chronic cough caused presumably by the accidental inhalation of lanthanum carbonate granules for oral use by a patient taking lanthanum carbonate to treat kidney disease (Oka et al., 2020). The authors suggested that the cough was caused by the mechanical stimulation by the granules. The Panel does not consider this paper as relevant for the current assessment and retains the conclusions previously reached on user safety.

The Panel concludes that the handling of the additive lanthanum carbonate octahydrate is safe for users.

3.3. Efficacy

To support the efficacy of the additive as a phosphate binder in cats, the applicant made reference to the efficacy studies submitted in a previous application for the same additive and already assessed by the FEEDAP Panel (EFSA, 2007). In that opinion, the FEEDAP Panel concluded based on the results of six trials in cats, that lanthanum carbonate octahydrate reduces significantly the phosphorus absorption and bioavailability in adult cats at the lowest recommended use level of 1,500 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 and currently authorised. Therefore, the conclusions reached in the previous assessment fully apply to the current application.

In addition, the applicant performed a literature search on the effects of lanthanum carbonate octahydrate (or the commercial preparations) on renal function. The protocol used was similar to the one used in the search for safety (see Section 3.2.1), but no limits were set for time. The search strategy (including keywords relevant to the active substance and efficacy) and inclusion and exclusion criteria were provided.

From this literature search, a total of 13 papers were considered relevant, 8 of which reported studies in cats. However, none of these papers was further considered as they either referred to studies done in cats suffering of chronic kidney disease, assessed parameters not relevant to the efficacy of the additive in reducing phosphate absorption or reported the same studies already assessed in the previous opinion of the Panel (EFSA, 2007).

Considering the above, the Panel concludes that lanthanum carbonate octahydrate is efficacious as a phosphate binder in adult cats at the proposed conditions of use (1,500 mg/kg complete feed).

4. Conclusions

The additive lanthanum carbonate octahydrate is safe for adult cats at the maximum recommended level of 7,500 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 as a phosphate binder in adult cats at the proposed conditions of use (minimum inclusion level 1,500 mg/kg complete feed).

5. Documentation provided to EFSA/Chronology

	Event
15/12/2020	Dossier received by EFSA. Lanthan One (lanthanum carbonate octahydrate) for cats. Submitted by Porus GmbH
18/12/2020	Reception mandate from the European Commission
21/03/2021	Application validated by EFSA – Start of the scientific assessment

	Event
20/05/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation/safety for the target animals and user
15/06/2021	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
1/07/2021	Comments received from Member States
21/07/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
25/10/2021	Reception of spontaneous submission of supplementary information
27/01/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
CHO	Chinese hamster ovary
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
ICES	International Council for the Exploration of the Sea
ICP-AES	inductively coupled plasma-atomic emission spectrometry
NCE	normochromatic erythrocytes
OECD	Organisation for Economic Co-operation and Development
PCBs	dioxin-like polychlorinated biphenyls
PCDDs	polychlorinated dibenzodioxins
PCDFs	polychlorinated dibenzofurans
PCE	polychromatic erythrocytes
RH	relative humidity
TEQ	toxic equivalent
UDS	unscheduled DNA Synthesis
WHO	World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the methods of the analysis for lanthanum carbonate octahydrate

In the current application an authorisation is sought under Article 4(1) for lanthanum carbonate octahydrate under the category/functional group 4(d) "zootechnical additives"/"other zootechnical additives", according to the classification system of Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the feed additive for cats.

According to the Applicant, the feed additive (lanthanum carbonate octahydrate) consists of a minimum of 85% (w/w) of lanthanum carbonate octahydrate as an active substance. The Applicant specified also the content of lanthanum and carbonate in the feed additive which is ranging from 43 to 49% (w/w) for lanthanum and 27 to 33% (w/w) for carbonate. The additive is intended to be incorporated directly into feedingstuffs with its levels ranging from 1.5 to 7.5 g/kg feedingstuffs.

For the determination of lanthanum carbonate octahydrate in the feed additive the Applicant proposed methods for the quantification of carbonate and lanthanum. For the quantification of the carbonate in the feed additive the EURL recommends for official control the European Union method (Commission Regulation (EC) No 152/2009, Annex III,O) based on carbonate decomposition in hydrochloric acid.

For the quantification of lanthanum in the feed additive and feedingstuffs the Applicant proposed a single-laboratory validated and further verified method based on inductively coupled plasma-atomic emission spectrometry (ICP-AES). The EURL recommends instead for official control the sample preparation described in the CEN standard methods, namely EN 15621 or EN 15510, followed by the above mentioned ICP-AES method for the determination of lanthanum in the feed additive and feedingstuffs.

The methods recommended by the EURL in the frame of the current application were previously evaluated and recommended by the EURL in the frame of the dossier FAD-2011-0021 and further included the Commission Implementing Regulations (EU) 2019/913 and (EU) 842/2012.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.