# COMMISSION REGULATION (EC) No 163/2008

## of 22 February 2008

## concerning an authorisation of the preparation Lanthanum carbonate octahydrate (Lantharenol) as a feed additive

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns a request for authorisation of the preparation Lanthanum carbonate octahydrate (Lantharenol), as a feed additive for cats, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 18 September 2007 that the preparation Lanthanum carbonate octahydrate (Lantharenol) does not have adverse effect on animal health or the environment and does not pose concerns for human health relative to incidental exposure to the additive [2]. It further concluded that that preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. Lantharenol has shown to decrease the phosphorus excretion via urine. The opinion of the Authority does not recommend appropriate measures for user safety. It considers that there is a need for specific requirements of post-market monitoring to recognise any long-term adverse effects in cats. This opinion also verifies the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

The preparation 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*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

[1] OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

[2] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on safety and efficacy of Lantharenol (Lanthanum carbonate octahydrate) as a feed additive for cats according to Regulation (EC) No 1831/2003, summary. Adopted on 18 September 2007. The EFSA Journal (2007) 542, 1-15.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 February 2008.

*For the Commission*
Markos KYPRIANOU
*Member of the Commission*

*ANNEX*

| Identification number of the additive | Name of the holder of authorisation | Additive (Trade name) | 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/kg of complete feedingstuff with a moisture content of 12 % | | | |
| **Category of zootechnical additives. Functional group: other zootechnical additives (decrease in phosphorus excretion via urine)** | | | | | | | | | |
| 4d1 | Bayer HealthCare AG | Lanthanum carbonate octahydrate (Lantharenol) | Additive composition:<br>Preparation of Lanthanum carbonate octahydrate.<br>At least 85 % Lanthanum carbonate octahydrate as active substance.<br>Characterisation of the active substance:<br>Lanthanum carbonate octahydrate<br>$La_2(CO_3)_3 \cdot 8H_2O$<br>CAS-Number 6487-39-4<br>Analytical method (1)<br>Inductively coupled plasma optical emission spectrometry (ICP-OES). | Cats | — | 1 500 | 7 500 | Post-market monitoring plan on chronic adverse effects is required.<br>In the directions for use of the additive:<br>— for adults cats,<br>— recommended dose of inclusion in moist feed with 20-25 % dry matter content: 340 to 2 100 mg per kg,<br>— avoid simultaneous use of feeds with high level of phosphorus. | 6 March 2018 |

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives