Commission Implementing Regulation (EU) 2020/1370 of 1 October 2020 concerning the authorisation of a preparation of lanthanide citrate as a feed additive for weaned piglets (holder of authorisation Treibacher Industrie AG) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1370

of 1 October 2020

concerning the authorisation of a preparation of lanthanide citrate as a feed additive for weaned piglets (holder of authorisation Treibacher Industrie 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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of lanthanide citrate. 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 the preparation of lanthanide citrate as a feed additive for weaned piglets to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 16 April 2013[(2)], 20 April 2016[(3)] and 12 November 2019[(4)] that, under the proposed conditions of use, the preparation of lanthanide citrate does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that although the acute respiratory toxicity data indicate that the dust is of low toxicity, prolonged or repeated exposure to the additive should be avoided. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive has the potential to be efficacious in improving the growth of weaned piglets. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of lanthanide citrate shows that the conditions for authorisation, as 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 Plants, Animals, Food and Feed,

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 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, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1370. (See end of Document for details)*

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	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 of additive/ kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters).									
4d21	Treibacher Industrie AG	Lanthanide citrate	***Additive composition*** Preparation of lanthanide citrate containing: Lanthanide citrate ≥ 65 % Sodium 8-12 % Chloride 8-12 % Water < 10 % Solid form	Weaned piglets		250	250	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.	*22.10.2030*
			Characterisation of active substance Lanthanide citrate Lanthanum 8,5 ± 0,9 % Chemical formula $C_6H_5LaO_7$ CAS-Number: 3002-52-6 Cerium 16,3 ± 1,6 %,					2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to	

a 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