

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1525

of 13 September 2022

concerning the authorisation of L-lysine monohydrochloride and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* CGMCC 14498 as feed additives for all animal species

(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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-lysine monohydrochloride and L-lysine sulphate. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 14498 as feed additives for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 November 2021 ⁽²⁾ that, under the proposed conditions of use, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 14498, when supplemented to diets in appropriate amounts, do not have an adverse effect on animal health, consumer safety or the environment. With respect to the safety of the user of those additives, the Authority could not conclude on the potential of L-lysine monohydrochloride to be toxic by inhalation and on the potential of L-lysine monohydrochloride and L-lysine sulphate to be irritant to skin or eyes, or on their potential to be a dermal sensitiser. Further, the Authority concluded that they are considered an efficacious source of the essential amino acid L-lysine for animal nutrition and that in order to be efficacious in ruminants, the additives should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) In view of the Authority's opinion, the Commission therefore considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives.
- (6) The assessment of L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 14498 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2021;19(12):6980.

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as feed additives 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, 13 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 additive/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c322iii	-	L-lysine monohydrochloride	<i>Additive composition</i> Preparation of L-lysine monohydrochloride with a minimum of 78,8 % L-lysine and with a moisture ≤ 1 % Powder form <i>Characterisation of the active substance</i> L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium glutamicum</i> CGMCC 14498 Chemical formula: C ₆ H ₁₅ ClN ₂ O ₂ CAS Number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾ For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph'	All species	-	-	-	1. The L-lysine content shall be indicated on the labelling of the additive. 2. The additive can be used via water for drinking. 3. Declarations to be made on the labelling of the additive and pre-mixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 4. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and pre-mixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	4.10.2032

			For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD).						
3c328		L-lysine sulphate	<i>Additive composition</i> Preparation of L-lysine sulphate with a minimum content of 73,0 % (L-lysine ≥ 55,0 % and other amino acids ≥ 10 %) <i>Powder form</i>	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. The additive can be used via water for drinking.	4.10.2032

			<i>Characterisation of the active substance</i> L-lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> CGMCC 14498 Chemical formula: $[C_6H_{14}N_2O_2]_2SO_4$ CAS number: 60343-69-3					3. Declarations to be made on the labelling of the additive and pre-mixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 4. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and pre-mixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	
			<i>Analytical methods ⁽¹⁾</i> For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: — European Pharmacopoeia Monograph 20301 For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F).						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en