

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/1163****of 14 June 2023****concerning the authorisation of L-Lysine monohydrochloride and L-Lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 17927 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 <sup>(1)</sup>, 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 L-Lysine monohydrochloride and L-Lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 17927. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of L-Lysine monohydrochloride and L-Lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 17927 as feed additives for all animal species, to be classified in the additive category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2022 <sup>(2)</sup> that, under the proposed conditions of use L-Lysine monohydrochloride and L-Lysine sulphate produced by *Corynebacterium glutamicum* CGMCC 17927, do not have an adverse effect on animal health, consumer safety or the environment.
- (5) The Authority concluded that exposure through inhalation to L-lysine monohydrochloride and L-Lysine sulphate produced with *Corynebacterium glutamicum* CGMCC 17927 is considered very likely and that in the absence of data, it cannot conclude on the potential of both additives to be irritant for skin and eyes or to be dermal sensitisers.
- (6) The Authority concluded that the additives have the potential to be efficacious for all animal species. The Authority does 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of L-lysine monohydrochloride and L-Lysine sulphate produced with *Corynebacterium glutamicum* CGMCC 17927 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. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of users of the additives.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2022;20(10):7613.

- (8) In view of the Authority's opinion, the label of the additives and premixtures should raise awareness that 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. In addition, the Commission considers that a maximum level should be set up for L-lysine sulphate due to the potential adverse effects from the intrinsic high sulphate content in the additive. The level of 10 000 mg/kg of complete feed was regarded as safe according to the Authority's opinion of 16 June 2015 <sup>(3)</sup> issued for another L-lysine sulphate.
- (9) 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*

**Authorisation**

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 additives in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

**Entry into force**

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, 14 June 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(3)</sup> EFSA Journal 2015;13(7):4155

## ANNEX

Identification number of the additive	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 feed with a moisture content of 12 %			
<b>Category of nutritional additives. Functional group: amino acids, their salts and analogues</b>								
3c322IV	L-lysine monohydrochloride	<p><i>Additive composition</i> L-lysine monohydrochloride with a minimum content of 78,8 % of L-Lysine on a dry matter basis and maximum moisture content of 1 % Solid form</p> <p><i>Characterisation of the active substance</i> L-lysine monohydrochloride produced by <i>Corynebacterium glutamicum</i> CGMCC 17927] Chemical formula: C<sub>6</sub>H<sub>14</sub>N<sub>2</sub>O<sub>2</sub> CAS number: 657-27-2</p> <p><i>Analytical method</i> <sup>(1)</sup> For the identification of L-lysine monohydrochloride in the feed additive: Food Chemical Codex 'L-lysine monohydrochloride monograph' For the quantification of lysine in the feed additives 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 and compound feed: – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)</p>	All species	-			<ol style="list-style-type: none"> <li>1. The lysine content shall be indicated on the labelling of the additive</li> <li>2. The additive may be used via water for drinking.</li> <li>3. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking.</li> <li>4. The label of the additive and premixture shall indicate the following: 'The supplementation with L-lysine monohydrochloride, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.'</li> <li>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing eye and skin protective equipment.</li> </ol>	6 July 2033

		For the quantification of lysine in water: – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)						
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(<sup>4</sup>) 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)

Identification number of the additive	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 %			
<b>Category of nutritional additives. Functional group: amino acids, their salts and analogues</b>								
3c329	L-lysine sulphate	<p><i>Additive composition</i> L-lysine sulphate with a minimum L-lysine content of 55 % on dry matter basis and a maximum content of:</p> <ul style="list-style-type: none"> <li>— 4 % moisture;</li> <li>— 26,5 % sulphate;</li> <li>— 0,8 % free amino acids other than lysine</li> </ul> <p>Solid form</p> <p><i>Characterisation of the active substance</i> L-lysine sulphate produced by <i>Corynebacterium glutamicum</i> CGMCC 17927 Chemical formula: C<sub>12</sub>H<sub>28</sub>N<sub>4</sub>O<sub>4</sub>-O<sub>4</sub>S CAS number: 60343-69-3</p> <p><i>Analytical method</i> <sup>(1)</sup> For the identification of sulphate in the feed additive (L-lysine sulphate): European Pharmacopoeia monograph 20301 For the quantification of lysine in the feed additives and premixtures (containing more than 10 % lysine): – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180</p>	All species	-	-	10 000	<ol style="list-style-type: none"> <li>1. The lysine content shall be indicated on the labelling of the additive.</li> <li>2. The additive may be used via water for drinking.</li> <li>3. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking.</li> <li>4. The label of the additive and premixture shall indicate the following: ‘The supplementation with L-lysine sulphate, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.’</li> <li>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing eye and skin protective equipment.</li> </ol>	6 July 2033

		<p>For the quantification of lysine in premixtures and compound feed: – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)</p> <p>For the quantification of lysine in water: – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or – ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)</p>						
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(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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)