

COMMISSION IMPLEMENTING REGULATION (EU) 2021/669**of 23 April 2021****concerning the authorisation of technically pure L-lysine monohydrochloride and liquid L-lysine base produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP 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 authorisation.
- (2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of liquid L-lysine base and technically pure L-lysine monohydrochloride as nutritional feed additives for use in feed and in water for drinking for all animal species. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the authorisation of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP 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 opinions of 30 September 2020 ⁽²⁾ and 18 November 2020 ⁽³⁾ ⁽⁴⁾ that, under the proposed conditions of use, L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP do not have an adverse effect on animal health, consumer health or the environment. The Authority could conclude on the safety for the user of the L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* KCCM 80216 and *Corynebacterium glutamicum* KCTC 12307BP. It stated that of L-lysine monohydrochloride, technically pure, and L-lysine base, liquid, produced by *Corynebacterium casei* KCCM 80190 are considered hazardous by inhalation and that L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 is a mild eye irritant. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP, are effective sources of the essential amino acid L-lysine for all animal species. For the supplemental L-lysine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. In its opinions, the Authority referred to a previous statement concerning potential nutritional imbalances for amino acids and hygienic concerns, when they are administered via water for drinking. However, the Authority did not propose a maximum content for the supplementation with L-lysine. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-lysine as amino acid via water for drinking.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2020;18(11):6285.⁽³⁾ EFSA Journal 2020;18(12): 6333.⁽⁴⁾ EFSA Journal 2020;18(12): 6334.

- (5) 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive 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,

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the category 'nutritional additives' and 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, 23 April 2021.

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.**

3c320	-	L-lysine base, liquid	<p><i>Additive composition:</i> Aqueous solution of L-lysine with a minimum of 50 % L-lysine.</p> <p><i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Corynebacterium casei</i> KCCM 80190 Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 56-87-1</p> <p><i>Analytical methods</i> (1): 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).</p>	All species	-	-	-	<ol style="list-style-type: none"> The lysine content shall be indicated on the labelling of the additive. L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation. The additive can be also used via water for drinking. Declarations to be made on the labelling of the additive and premixtures: '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.' For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by 	16 May 2031
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			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).					such procedures and measures, the additive and pre-mixtures shall be used with appropriate personal protective equipment, including breathing protection, safety glasses and gloves.	
3c326	-	L-lysine base, liquid	<p><i>Additive composition:</i> Aqueous solution of L-lysine with a minimum of 50 % L-lysine.</p> <p><i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 56-87-1</p> <p><i>Analytical methods</i> ⁽¹⁾: 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.</p>	All species	-	-	-	<ol style="list-style-type: none"> 1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation. 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 	16 May 2031

			<p>For the quantification of lysine in premixtures, compound feed and feed materials:</p> <ul style="list-style-type: none"> — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). <p>For the quantification of lysine in water:</p> <ul style="list-style-type: none"> — 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). 					appropriate personal protective equipment, including breathing protection.	
3c322	L-lysine monohydrochloride, technically pure	<p><i>Additive composition:</i> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %.</p> <p><i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium casei</i> KCCM 80190 Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾:</p>	All species	-	-	-	<ol style="list-style-type: none"> 1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation. 3. The additive can be also used via water for drinking. 4. Declarations to be made on the labelling of the additive and premixtures: "The supplementation with L-lysine, in particular via water for drinking, should take into account 	16 May 2031	

			<p>For the identification of L-lysine monohydrochloride in the feed additive:</p> <ul style="list-style-type: none"> — Food Chemical Codex 'L-lysine monohydrochloride monograph' <p>For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine:</p> <ul style="list-style-type: none"> — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. <p>For the quantification of lysine in premixtures, compound feed and feed materials:</p> <ul style="list-style-type: none"> — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). <p>For the quantification of lysine in water:</p> <ul style="list-style-type: none"> — 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>all essential and conditionally essential amino acids in order to avoid imbalances.'</p> <p>5. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air ^(?).</p> <p>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 premixtures shall be used with appropriate personal protective equipment, including breathing protection, safety glasses and gloves.</p>	
3c327	L-lysine monohydrochloride, technically pure	<p><i>Additive composition:</i> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %.</p> <p><i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP Chemical formula: NH₂-(CH₂)₄-CH(NH₂)-COOH CAS Number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾: For the identification of L-lysine monohydrochloride in the feed additive:</p>	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive.	16 May 2031	

		<p>— Food Chemical Codex 'L-lysine monohydrochloride monograph'</p> <p>For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180.</p> <p>For the quantification of lysine in premixtures, compound feed and feed materials:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).</p>					<p>2. L-lysine monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation.</p> <p>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation and eye contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection and safety glasses.</p>	
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(¹) 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>

(²) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (*EFSA Journal* 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14 (bacterial endotoxins).