

ANNEX

Identification number of the additive	Name of the 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 /kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c331	L-lysine monohydrochloride	Additive composition: L-lysine monohydrochloride with a minimum content of 78 % of L-Lysine on a dry matter basis Solid form ----- Characterisation of the active substance: L-lysine monohydrochloride produced with <i>Corynebacterium glutamicum</i> CGMCC 23982 Chemical formula: C₆H₁₄ N₂O₂ CAS number: 657-27-2 ----- Analytical methods¹: For the identification of L-lysine monohydrochloride in the feed additive: – Food Chemical Codex “L-lysine monohydrochloride monograph” For the determination of lysine in the	All animal species	–	-	-	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and stability in water for drinking shall be indicated. 2. The additive may be used via water for drinking. 3. Feed business operators shall ensure that L-lysine monohydrochloride is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The label of the additive and premixtures shall indicate the following: ‘The supplementation with L-lysine monohydrochloride, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.’ 6. For users of the additive and	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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

		feed additive: – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 For the determination of lysine in premixtures: – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 or – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009² For the determination of lysine in compound feed: – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 For the determination of lysine in water for drinking: – Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)					premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection.	
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² Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009; ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).