

## ANNEX

Identi- fication number of the feed 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 authorisa- tion
					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c320	L-Lysine base, liquid	<b>Additive composition:</b> Preparation of L-lysine with a minimum content of 50% L-lysine - Aqueous solution  ----- <b>Characterisation of the active substance:</b> L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> NRRL B- 67439 or <i>Corynebacterium glutamicum</i> NRRL B- 67535 Chemical formula: NH <sub>2</sub> -(CH <sub>2</sub> ) <sub>4</sub> - CH(NH <sub>2</sub> )-COOH CAS number: 56-87-1  ----- <b>Analytical methods<sup>1</sup>:</b> 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	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive.  2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation and for the skin and eyes. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protection.  3. The additive may be also used via water for drinking.  4. Declarations to be made on the labelling of the additive and premixtures: ‘The supplementation	30.7.2030

<sup>1</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).

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					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<p>detection (IEC-VIS/FLD) – EN ISO 17180</p> <p>For the quantification of lysine in premixtures, compound feed and feed materials:</p> <ul style="list-style-type: none"><li>- ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009</li></ul> <p>For the quantification of lysine in water:</p> <ul style="list-style-type: none"><li>- ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)</li></ul>					with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.’	
3c320ii	L-Lysine base, liquid	<p><b>Additive composition:</b></p> <p>Preparation of L-lysine with a minimum content of 50% L-lysine - Aqueous solution</p> <p>-----</p> <p><b>Characterisation of the active substance:</b></p> <p>L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> NRRL B-68248</p> <p>Chemical formula: NH<sub>2</sub>-(CH<sub>2</sub>)<sub>4</sub>-CH(NH<sub>2</sub>)-COOH</p> <p>CAS number: 56-87-1</p> <p>-----</p>	All species	-	-	-	<p>1. The lysine content shall be indicated on the labelling of the additive.</p> <p>2. Declarations to be made on the labelling of the additive and premixtures: ‘The supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.’</p>	30.7.2030

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					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<b>Analytical methods<sup>1</sup>:</b> 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 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						
3c322	L-lysine monohydrochloride, technically pure	<b>Additive composition:</b> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %.  ----- <b>Characterisation of the active substance:</b> L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium glutamicum</i> NRRL-B-67439 or	All species	-	-	-	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.For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by	

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					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<p><i>Corynebacterium glutamicum</i> NRRL B-67535 or</p> <p><i>Corynebacterium glutamicum</i> CGMCC 7.266.</p> <p>Chemical formula: NH<sub>2</sub>-(CH<sub>2</sub>)<sub>4</sub>-CH(NH<sub>2</sub>)-COOH</p> <p>CAS Number: 657-27-2</p> <p><b>Analytical methods<sup>1</sup>:</b></p> <p>For the identification of L-lysine monohydrochloride in the feed additive:</p> <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 photometric 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 photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009</p> <p>For the quantification of lysine in water:</p>					<p>inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</p> <p>4.The additive may be also used via water for drinking.</p> <p>5.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 conditional essential amino acids in order to avoid imbalances.’</p>	

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					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<p>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS).</p>						
3c325	L-lysine sulphate	<p><b>Additive composition:</b></p> <p>Granulate with a minimum L-lysine content of 52 % and a maximum content of 24 % sulphate.</p> <p>-----</p> <p><b>Characterisation of the active substance:</b></p> <p>L-lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> CGMCC 7.266</p> <p>Chemical formula: C<sub>12</sub>H<sub>28</sub>N<sub>4</sub>O<sub>4</sub>•H<sub>2</sub>SO<sub>4</sub>/[NH<sub>2</sub>-(CH<sub>2</sub>)<sub>4</sub>-CH(NH<sub>2</sub>)-COOH]<sub>2</sub>SO<sub>4</sub></p> <p>CAS number: 60343-69-3</p> <p>-----</p> <p><b>Analytical methods<sup>1</sup>:</b></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</p>	All species	-	-	10 000	<p>1.The L-lysine content shall be indicated on the labelling of the additive.</p> <p>2.L-lysine sulphate 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 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 breathing protection.</p> <p>4.The additive may be also used via water for drinking.</p>	

Identi- fication number of the feed 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 authorisa- tion
					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		<p>photometric detection (IEC-VIS/FLD) – EN ISO 17180</p> <p>For the identification of sulphate in the feed additive:</p> <p>— European Pharmacopoeia Monograph 20301</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 photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009</p> <p>For the quantification of lysine in water:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)</p>					5.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 conditional essential amino acids in order to avoid imbalances.’	