

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								
3c367	L-arginine	Additive composition: L-arginine ≥ 98 % (on a dry matter basis) Solid form ----- Characterisation of the active substance: L-arginine produced with <i>Corynebacterium glutamicum</i> KCCM 80387 IUPAC name: (S)-2-amino-5- guanidinopentanoic acid Chemical formula: C ₆ H ₁₄ N ₄ O ₂ CAS number: 74–79-3 ----- Analytical method¹: For the identification of L-arginine in the feed additive: - Food Chemical Codex "L-arginine monograph" For the determination of arginine in the feed additive and water: - Ion-exchange chromatography coupled	All animal species	-	-	-	<ol style="list-style-type: none">1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water shall be indicated.2. The additive may be used via water for drinking.3. Feed business operators shall ensure that L-arginine 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- arginine, in particular via water	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

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.

		<p>with post-column derivatisation and optical detection (IEC-VIS);</p> <p>For the determination of arginine in premixtures and compound feed: - Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) 152/2009.</p>					<p>for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.'</p> <p>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 eye and breathing protective equipment.</p>	
Category: Sensory additives. Functional group: Flavouring compounds								
3c367	L-arginine	<p>Additive composition: L-arginine ≥ 98 % (on a dry matter basis)</p> <p>Solid form -----</p> <p>Characterisation of the active substance: L-arginine produced with <i>Corynebacterium glutamicum</i> KCCM 80387 IUPAC name: (S)-2-amino-5-guanidinopentanoic acid Chemical formula: C₆H₁₄N₄O₂ CAS number: 74-79-3</p>	All animal species	-	-	-	<p>1. The additive shall be incorporated into the feed in the form of a premixture.</p> <p>2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated.</p> <p>3. On the label of the additive and premixture the following shall be indicated: 'Recommended maximum content of the active</p>	<p>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</p>

		<p>-----</p> <p>Analytical method²:</p> <p>For the identification of L-arginine in the feed additive:</p> <ul style="list-style-type: none"> - Food Chemical Codex "L-arginine monograph" <p>For the determination of arginine in the feed additive :</p> <ul style="list-style-type: none"> - Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS); <p>For the determination of arginine in premixtures:</p> <ul style="list-style-type: none"> - Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) 152/2009. 					<p>substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.’</p> <ol style="list-style-type: none"> 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the content referred to in point 3. 5. The moisture content shall be indicated on the label of the additive. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 eye and breathing protective equipment. 	
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² 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.