

ANNEX

Identification number of the feed 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								
3c366	L-arginine	<p>Additive composition: L-arginine ≥ 98,5 % (on a dry matter basis)</p> <p>Solid form</p> <p>-----</p> <p>Characterisation of the active substance: L-arginine produced with <i>Corynebacterium glutamicum</i> KCCM 80393 IUPAC name: (S)-2-amino-5-guanidinopentanoic acid Chemical formula: C₆H₁₄N₄O₂ CAS number: 74-79-3</p> <p>-----</p> <p>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:</p>	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 the 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-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 for drinking, shall take into 	[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.

		<ul style="list-style-type: none"> - Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD or IEC-VIS) <p>For the determination of arginine in premixtures:</p> <ul style="list-style-type: none"> - Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 or - Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) <p>For the determination of arginine in compound feed:</p> <ul style="list-style-type: none"> - Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 <p>For the determination of arginine in water:</p> <ul style="list-style-type: none"> - Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) 				<p>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 its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.</p>	
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