

ENANNEX

Identifi-cation 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									
3c442	L-tryptophan	<p>Additive composition Powder with a minimum content of L-tryptophan of 98 % (on a dry matter basis) and ≤ 0,5% water</p> <p>Maximum content of 10 mg/kg 1,1'-ethylened-bis-L-tryptophan (EBT)</p> <p>Characterisation of the active substance L-tryptophan produced with <i>Escherichia coli</i> CGMCC 7.460</p> <p>Chemical formula: C₁₁H₁₂N₂O₂</p> <p>CAS number: 73-22-3</p> <p>Analytical method¹ For the identification of L-tryptophan in the feed additive:</p> <p>– Food Chemical Codex "L-tryptophan monograph"</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 in water shall be indicated. 2. The additive may be used via water for drinking. 3. The labelling of the additive and premixtures shall indicate the following: <p>— 'The supplementation with L-tryptophan, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.'</p> 	[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.

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Category: nutritional additives. Functional group: amino acids, their salts and analogues									
		<p>For the determination of tryptophan in the feed additive and premixtures:</p> <ul style="list-style-type: none"> – High performance liquid chromatography with fluorescence detection (HPLC-FLD) - EN ISO 13904 <p>For the determination of tryptophan in compound feed:</p> <ul style="list-style-type: none"> – High performance liquid chromatography with fluorescence detection (HPLC-FLD) - Commission Regulation (EC) No 152/2009 				<p>4. Feed business operators shall ensure that L-thryptophan is rumen protected when administered to ruminants.</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 air².</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 skin, eye and breathing protective equipment.</p>			

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Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).