

ANNEX

Identi- fication 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 authorisa- tion
					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c443i	L-tryptophan	Additive composition L-tryptophan 1,1'- ethylidene-bis-L-tryptophan (EBT) ≤ 10 mg/kg Solid form Characterisation of the active substance L-tryptophan ≥ 98 % (on a dry matter basis) produced with <i>Escherichia coli</i> CCTCC M 2024517 IUPAC name: (2S)-2-amino-3-(1H-indol- 3-yl) propanoic acid Chemical formula: C ₁₁ H ₁₂ N ₂ O ₂ CAS number: 73-22-3 Analytical method¹	All animal species	-	-	-	<div>1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment and in water for drinking shall be indicated.</div> <div>2. The additive may be used via water for drinking.</div> <div>3. Feed business operators shall ensure that L-tryptophan is rumen protected, when fed to ruminants.</div> <div>4. The moisture content shall be indicated on the label of the additive.</div> <div>5. The labelling of the additive and premixtures shall indicate the following: ‘The supplementation with L-</div> <td>[10 years from the date of entry into force of this Regulation. To be completed by the OP.]</td>	[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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		<p>For the identification of L-tryptophan in the feed additive:</p> <p>- Food Chemical Codex “L-tryptophan” monograph</p> <p>For the determination of tryptophan in the feed additive and premixtures:</p> <p>- High performance liquid chromatography with fluorescence detection (HPLC-FLD) - EN ISO 13904</p> <p>For the determination of tryptophan in compound feed:</p> <p>- High performance liquid chromatography with fluorescence detection (HPLC-FLD) - Commission Regulation (EC) 152/2009</p> <p>For the determination of tryptophan in water for drinking:</p> <p>- High performance liquid chromatography with fluorescence detection (HPLC-FLD)</p>					<p>tryptophan, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances.’</p> <p>6. 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>7. 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>	

² Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

