

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									
3c385	L-isoleucine	<p>Additive composition Powder with a minimum content of L-isoleucine of 93,5 % (on a dry matter basis) and a maximum moisture content of 2 %</p> <p>Characterisation of the active substance L-isoleucine produced with <i>Corynebacterium glutamicum</i> CGMCC 20437</p> <p>Chemical formula: C₆H₁₃NO₂</p> <p>CAS number: 73-32-5</p> <p>Analytical method¹ For the identification of L-isoleucine in the feed additive: – Food Chemical Codex "L-isoleucine monograph";</p>	All animal species	-			<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, 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-isoleucine is rumen protected when administered to ruminants. 4. The labelling of the additive and premixtures shall indicate the following: ‘The supplementation with L-isoleucine, in particular via water for drinking, shall take into account all essential and conditionally essential amino 	[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 isoleucine in the feed additive:</p> <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 isoleucine in premixtures:</p> <ul style="list-style-type: none"> – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) or – Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009; <p>For the determination of isoleucine 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 isoleucine in water:</p>				<p>acids in order to avoid imbalances.'</p> <p>5. 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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		– Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS).						