EN

ANNEX

Identification 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 authorisation
					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c384ii	L-isoleucine	**Additive composition** L-isoleucine Solid form **Characterisation of the active substance** L-isoleucine ≥ 90 % (on a dry matter basis) produced with *Corynebacterium glutamicum* CCTCC M 2022764 IUPAC name: (2S,3S)-2-amino-3-methylpentanoic acid Chemical formula: $C_6H_{13}NO_2$ CAS number: 73-32-5 **Analytical method**[1] For the identification of L-isoleucine in the feed additive:	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions, stability to heat treatment and 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-isoleucine is rumen protected, when fed to ruminants. 4. The moisture content shall be indicated on the label of the additive. 5. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-isoleucine, in particular via water	[*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								
		− Food Chemical Codex "L-isoleucine monograph"; For the determination of isoleucine in the feed additive: − Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD or IEC-VIS); For the determination of isoleucine in premixtures: − 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; For the determination of isoleucine in compound feed: − Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009;					for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid nutritional imbalances'. 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.	

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Category: nutritional additives. Functional group: amino acids, their salts and analogues								
		For the determination of isoleucine in water for drinking: − Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS).						