

EN

ANNEX

Identification number of the additive	Name of the feed 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
					Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements								
3b411	Copper bislysinate	Additive composition Copper bislysinate complex Solid powder form Nickel: maximum 20 mg/kg Characterisation of the active substance Copper bislysinate complex with a content of copper ≥ 14,5 % and L-lysine HCl ≥ 84,0 % Produced by a chemical reaction in several steps of copper (II) oxide with L-Lysine hydrochloride Chemical formula: Cu(C6H13N2O2)2 × 2HCl CAS number: 53383-24-7 Purity criteria: Copper bislysinate: ≥ 99%	Bovines	Before the start of rumination	-	15	1. The additive shall be incorporated into feed in the form of a premixture. 2. The following words shall be included in the labelling: — For feed for sheep if the level of copper in the feed exceeds 10 mg/ kg: The level of copper in this feed may cause poisoning in certain breeds of sheep.’ — For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: ‘The level of copper in this feed may cause copper deficiencies in cattle grazing	[10 years from the date of entry into force of this Regulation. To be completed by the OP]
			Other bovines	-	-	30		
			Ovines	-	-	15		
			Caprines	-	-	35		
			Piglets suckling and weaned	Up to 4 weeks after weaning	-	150		
			Piglets	From 5-th week after weaning up to 8 weeks after weaning	-	100		

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					Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements								
		Analytical method ¹ For the determination of copper bislysinate complex in the feed additive: — Spectrophotometry For the determination of Lysine content in the feed additive: — Ion-exchange chromatography coupled to post-column derivatisation and optical detection IEC-VIS/FLD (EN ISO 17180). For the determination of total copper content in the feed additive: — Inductively coupled plasma atomic emission spectrometry ICP-AES) (EN 15510 or EN 15621) or — Atomic absorption spectrometry, AAS (EN ISO 6869) For the determination of total copper content in premixtures: — Inductively coupled plasma atomic emission spectrometry ICP-AES (EN 15510 or EN 15621) or — Atomic absorption spectrometry, AAS (EN ISO 6869) or	Crustaceans	-	-	50	pastures with high contents of molybdenum or sulphur.’ — ‘The lysine content of the additives should be considered when formulating feed.’ 3. 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.	
			Other animal species or categories	-	-	25		

¹Details 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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					Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements								
		– Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the determination of total copper in compound feed: – Inductively coupled plasma atomic emission spectrometry ICP-AES EN 15510 or EN 15621 or – Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 or EN ISO 6869) or – Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)						

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Category of nutritional additives. Functional group: compounds of trace elements								
3b411i	Copper bislysinate	Additive composition Preparation containing a minimum of 99,5 % of copper bislysinate complex with a minimum of 14 % of copper and a minimum of 84% of L- lysine HCl Granulated form Nickel: maximum 20 mg/kg Characterisation of the active substance Copper bislysinate complex with a content of copper ≥ 14,5 % and L-lysine HCl ≥ 84,0 % Produced by a chemical reaction in several steps of copper (II) oxide with L-lysine HCl Chemical formula: Cu(C ₆ H ₁₃ N ₂ O ₂) ₂ × 2HCl CAS number: 53383-24-7 Purity criteria: Copper bislysinate: ≥ 99%	Bovines	Before the start of rumination	-	15	1. The additive shall be incorporated into feed in the form of a premixture. 2. The following words shall be included in the labelling: — For feed for sheep if the level of copper in the feed exceeds 10 mg/ kg: The level of copper in this feed may cause poisoning in certain breeds of sheep.’ — For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: ‘The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.’	[10 years from the date of entry into force of this Regulation. To be completed by the OP]
			Other bovines	-	-	30		
			Ovines	-	-	15		
			Caprines	-	-	35		
			Piglets suckling and weaned	Up to 4 weeks after weaning	-	150		
			Piglets	From 5-th week after weaning up to 8 weeks after weaning	-	100		
			Crustaceans	-	-	50		

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					Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements								
		For the determination of total copper content in premixtures: – Inductively coupled plasma atomic emission spectrometry ICP-AES (EN 15510 or EN 15621) or – Atomic absorption spectrometry, AAS (EN ISO 6869) or – Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the determination of total copper in compound feed: – Inductively coupled plasma atomic emission spectrometry ICP-AES EN 15510 or EN 15621 or – Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 or EN ISO 6869) or – Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)						