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ANNEX

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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
					Content of the element (Cu) in mg/kg of complete feed with a moisture content of 12%			
Category: nutritional additives. Functional group: compounds of trace elements								
3b416	Copper (II)–betaine complex	**Additive composition:** Copper betaine complex with a minimum of 19% of copper and a minimum of 36% of betaine Nickel: maximum 77 mg/kg Solid form **Characterisation of the active substances:** Name: catena-[diaquasulphato-μ2-(trimethylammonio)acetato-copper(II)]; Chemical formula: $[Cu(H_2O)_2((CH_3)_3NCH_2COO)(SO_4)]n$ Specifications: Copper: minimum of 19%	Bovines before start of rumination	Before 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	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*
			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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Category: nutritional additives. Functional group: compounds of trace elements								
		Betaine: minimum 36% Sulphur: 9%–12% Moisture: maximum 5% **Analytical methods[1]:** For the quantification of total *copper* in the *feed additive*: - Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or - Atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total *copper* in the *premixtures*: - Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or - Atomic absorption spectrometry, AAS (ISO 6869) or - Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of total *copper* in the *compound feed*: - Inductively coupled plasma-atomic	Crustaceans			50	mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.' 3. Users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks of exposure by inhalation, dermal contact or eyes contact, in particular due to the content nickel. Where such risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and	
			Other animal species and categories			25		

[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

Identifi-cation 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
					Content of the element (Cu) in mg/kg of complete feed with a moisture content of 12%			
Category: nutritional additives. Functional group: compounds of trace elements								
		emission spectrometry, ICP-AES (EN 15621 or EN 15510) or - Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or - Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of *betaine* in the *feed additive*: - High performance liquid chromatography with refraction index detection (HPLC-RI) For the quantification of *sulphur* and *sulphate* in the *feed additive*: - Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621) For proving the formation of copper (II) betaine complex: - Powder X-ray diffraction (XRD).					breathing protection.	

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