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COMMISSION IMPLEMENTING REGULATION (EU) 2016/2261

of 15 December 2016

concerning the authorisation of copper(I) oxide as a feed additive for all animal species

(Text with EEA relevance)

(OJ L 342, 16.12.2016, p. 18)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2018/1039 of 23 July 2018	L 186	3	24.7.2018

▼B

COMMISSION IMPLEMENTING REGULATION (EU) 2016/2261

of 15 December 2016

concerning the authorisation of copper(I) oxide as a feed additive for all animal species

(Text with EEA relevance)

Article 1

The substance specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX

Identification number of the additive	Name of the holder of authorisation	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 Cu in mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b412	—	Copper(I) oxide	*Characterisation of the additive* Preparation of copper(I) oxide with — a minimum copper content of 73 %, — Sodium lignosulfonates between 12 % and 17 %, — 1 % Bentonite. Granulated form with particles < 50 μm: below 10 % *Characterisation of the active substance* Copper(I) oxide Chemical formula: Cu_2O CAS number: 1317-39-1 *Analytical methods* (1) For the identification of Cu_2O in the additive: — X-Ray diffraction (XRD).	All animal species	—	—	►**M1** Bovines: — Bovines before the start of rumination: 15 (total); — Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total) Piglets: — suckling and weaned up to 4 weeks after weaning: 150 (total); — from 5-th week after weaning up to 8 weeks after weaning: 100 (total). Crustaceans: 50 (total). Other animals: 25 (total). ◄	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	5 January 2027

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Identification number of the additive	Name of the holder of authorisation	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 Cu in mg/kg of complete feedingstuff with a moisture content of 12 %			
			For the quantification of the total copper content in the additive: — Titrimetry; or — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) — EN 15510. For the quantification of total copper content in premixtures: — Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) — EN 15510; or — Inductively Coupled Plasma Atomic Emission Spectrometry after pressure digestion (ICP-AES) — EN 15621. For the quantification of total copper content in feed materials and compound feed: — Atomic Absorption Spectrometry (AAS) — Commission Regulation (EC) No 152/2009; or					3. 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.’	

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Identification number of the additive	Name of the holder of authorisation	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 Cu in mg/kg of complete feedingstuff with a moisture content of 12 %			
			— Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES) — EN 15510; or — Inductively Coupled Plasma Atomic Emission Spectrometry after pressure digestion (ICP-AES) — EN 15621.						

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports