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COMMISSION IMPLEMENTING REGULATION (EU) No 667/2013

of 12 July 2013

concerning the authorisation of diclazuril as a feed additive for chickens reared for laying (holder of authorisation ►M1 Elanco GmbH ◄) and repealing Regulation (EC) No 162/2003

(Text with EEA relevance)

(OJ L 192, 13.7.2013, p. 35)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Regulation (EU) 2019/138 of 29 January 2019	L 26	1	30.1.2019

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COMMISSION IMPLEMENTING REGULATION (EU) No 667/2013

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concerning the authorisation of diclazuril as a feed additive for chickens reared for laying (holder of authorisation ►M1 Elanco GmbH ◄) and repealing Regulation (EC) No 162/2003

(Text with EEA relevance)

Article 1

The preparation specified in the Annex, belonging to the additive category 'coccidiostats and histomonostats' is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 162/2003 is repealed.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 2 February 2014 in accordance with the rules applicable before 2 August 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Coccidiostats and histomonostats										
51771	►**M1** Elanco GmbH ◄	Diclazuril 0,5 g/100 g (Clinacox 0,5 %)	*Additive composition* Diclazuril: 0,50 g/100 g Protein-poor soybean meal: 99,25 g/100 g Polyvidone K 30: 0,20 g/100 g Sodium hydroxide: 0,05 g/100 g *Characterisation of the active substance* Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro-4- (2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2 Related impurities: Degradation compound (R064318): ≤ 0,1 % Other related impurities (T001434, R066891, R068610, R070156, R070016): ≤ 0,5 % individually Total impurities: ≤ 1,5 % *Analytical method* (1) For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280 nm (Commission Regulation (EC) No 152/2009 (2)).	Chickens reared for laying	16 weeks	1	1	1. The additive shall be incorporated in compound feed in the form of a premixture. 2. Diclazuril shall not be mixed with other coccidiostats. 3. For safety: breathing protection, glasses and gloves shall be used during handling. 4. A post-market monitoring programme concerning the resistance to bacteria and *Eimeria* spp. shall be carried out by the holder of authorisation.	2 August 2023	Commission Regulation (EU) No 37/2010 (3)

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Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			For determination of diclazuril in poultry tissues: HPLC coupled to triple quadrupole mass spectrometer (MS/MS) using one precursor ion and two diagnostic product ions.							

([1]) Details of the analytical methods are available at the following address of the Community Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx
([2]) OJ L 54, 26.2.2009, p. 1.
([3]) OJ L 15, 20.1.2010, p. 1.