COMMISSION IMPLEMENTING REGULATION (EU) 2015/1417

of 20 August 2015

concerning the authorisation of diclazuril as a feed additive for rabbits for fattening and for breeding (holder of the authorisation Huvepharma NV)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of diclazuril. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of diclazuril, CAS number 101831-37-2, as a feed additive for rabbits for fattening and for breeding, to be classified in the additive category 'coccidiostats and histomonostas'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 10 December 2014 ([2]) that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, human health or the environment and is effective in controlling coccidiosis in rabbits for fattening and for breeding. It considers that there is a need for specific requirements of post-market monitoring to verify the resistance to Eimeria spp. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of diclazuril, CAS number 101831-37-2, shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex belonging to the additive category 'coccidiostats and histomonostas', 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*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2015; 13(1):3968.

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

Done at Brussels, 20 August 2015.

For the Commission
The President
Jean-Claude JUNCKER

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	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feeding stuff with a moisture content of 12 %				
Coccidiostats and histomonostats										
51775	Huvepharma NV	Diclazuril 0,5 g/100 g (Coxiril)	*Additive composition* Preparation of: Diclazuril: 5 g/kg. Starch: 15 g/kg. Wheat meal: 700 g/kg. Calcium carbonate: 280 g/kg. *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. Impurity D (1): ≤ 0,1 %. Any other single impurity: ≤ 0,5 %. Total impurities: ≤ 1,5 %. *Analytical method* (2) For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Commission Regulation (EC) No 152/2009 (3)).	Rabbits	—	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. Use prohibited at least two days before slaughter. 5. A post market monitoring programme concerning the resistance to Eimeria spp. shall be carried out by the holder of authorisation during the latter part of the period of the authorisation.	10 September 2025	Commission Regulation (EU) No 37/2010 (4) (— 2 500 µg diclazuril/kg of wet liver. — 1 000 µg diclazuril/kg of wet kidney. — 150 µg diclazuril/kg of wet muscle. — 300 µg diclazuril/kg of wet skin/fat.)

(1) European Pharmacopoeia monograph 1718 (Diclazuril for Veterinary use).
(2) 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.
(3) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).
(4) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).