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COMMISSION IMPLEMENTING REGULATION (EU) 2026/2061

of 17 September 2026

concerning the authorisation of a preparation of narasin and diclazuril (Interban) as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation: Elanco GmbH)

(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 an authorisation.

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

(3) The application concerns the authorisation of a preparation of narasin and diclazuril as a feed additive for chickens for fattening and chickens reared for laying, requesting that additive to be classified in the category 'coccidiostats and histomonostats'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 February 2026 ([2]) that the preparation of narasin and diclazuril is safe for the target species, as well as for consumers and the environment, when used at the proposed level of 50 mg narasin and 1 mg diclazuril/kg complete feed. It also concluded that the maximum residue limits currently in force for narasin and diclazuril are protective for the consumer at 0-day withdrawal. The Authority concluded that the preparation of narasin and diclazuril is not irritant to the skin, but should be considered a skin and respiratory sensitiser, inhalation and dermal exposure being considered a risk for the user, while it could not conclude on the eye irritation potential due to the lack of data. The Authority further concluded that the preparation of narasin and diclazuril is efficacious controlling coccidiosis in chickens for fattening when used at the proposed used level of 50 mg narasin and 1 mg diclazuril/kg complete feed and extended that conclusion to chickens reared for laying. It considered that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003. In addition, the Authority highlighted the danger of the additive for equine species, turkeys and rabbits, as well as the fact that simultaneous use with certain medicinal substances can be contraindicated.

(5) In view of the above, the Commission considers that the preparation of narasin and diclazuril satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. It is appropriate to provide for post-market monitoring of the resistance of *Eimeria* spp. to narasin and diclazuril. It is appropriate to provide for indicating in the directions for use that the additive is dangerous for certain species and that its simultaneous use with certain medicinal substances can be contraindicated. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal* 2026;24:e9963, https://doi.org/10.2903/j.efsa.2026.9963.

(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 histomonostats', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Entry into force

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.

Done at Brussels, 17 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %				
Category: coccidiostats and histomonostats										
51778	Elanco GmbH	Narasin 100 mg/g and diclazuril 2 mg/g (Interban)	*Additive composition* Preparation of — narasin: 90,0-110,0 g/kg — diclazuril: 1,8-2,2 g/kg — food-grade mineral oil — rice hulls qs 1 kg. Solid form. *Characterisation of the active substances* Narasin granulated containing: — Narasin: ≥ 100 mg/g, including: — narasin A: (2*R*)-2-{(2*R*,3*S*,5*S*,6*R*)-6-[(2*S*,3*S*,4*S*,6*R*)-6-{(2*S*,5*S*,7*R*,9*S*,10*S*,12*R*,15*R*)-2-[(2*R*,5*R*,6*S*)-5-ethyl-5-hydroxy-6-methyltetrahydro-2*H*-pyran-2-yl]-15-hydroxy-2,10,12-trimethyl-1,6,8-trioxadispiro[4.1.5^{7}.3^{5}]pentadec-13-en-9-yl}-3-hydroxy-4-methyl-5-oxooctan-2-yl]-3,5-dimethyltetrahydro-2*H*-pyran-2-yl} butanoic acid; $C43H_{72}O_{11}$; CAS number: 55134-13-9: ≥ 85 %; — narasin B, D and I.	Chickens for fattening Chickens reared for laying	—	50 (narasin) 1 (diclazuril)	50 (narasin) 1 (diclazuril)	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. The additive shall not be used simultaneously with other coccidiostats. 4. Indicate in the directions for use of the additive, premixtures and related feed: 'Dangerous for equines, turkeys and rabbits. This feed contains an ionophore: simultaneous use with certain medicinal substances, including tiamulin, is contra-indicated.'	8 October 2036	50 µg narasin/kg of all wet tissues Diclazuril: Commission Regulation (EU) No 37/2010 ([5])

Identification number of the additive	Name of the holder of authorisation	Name of the 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 feed with a moisture content of 12 %				
			— Fermentation mass. — Dipotassium phosphate. — Clays (> 99,9 % montmorillonite and < 0,1 % attapulgite). Produced by fermentation with *Streptomyces* spp. NRRL B-67771. Diclazuril: (±)- 2,6-dichloro-α-(4-chlorophenyl)-4-(4,5-dihydro-3,5-dioxo-1,2,4-triazin-11-2(3H)-yl) benzeneacetonitrile; $C_{17}H_9Cl_3N_4O_2$. CAS number: 101831-37-2. Total impurities A to I ([1]): ≤ 1,5 %. Produced by chemical synthesis. *Analytical methods* ([2]) For the determination of narasin in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis). For the determination of narasin in premixtures: High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183.					5. A post-market monitoring programme on the resistance of *Eimeria* spp. to narasin and diclazuril shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 ([4]). 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 breathing, eye and skin protective equipment.		

ELI: http://data.europa.eu/eli/reg_impl/2026/2061/oj

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						mg of active substance/kg of complete feed with a moisture content of 12 %				
			For the determination of narasin in compound feed: — High Performance Liquid Chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183 or — High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299. For the determination of diclazuril in the feed additive: High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV). For the determination of diclazuril in premixtures: High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV) – Commission Regulation (EC) No 152/2009 ([3]). For the determination of diclazuril in compound feed: — High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV) – Regulation (EC) No 152/2009 or — High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS) – EN 17299.						

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						mg of active substance/kg of complete feed with a moisture content of 12 %				
			For the determination of narasin in tissues: High Performance Liquid Chromatography coupled with tandem mass spectrometry – AOAC 2011.24.							

([1]) As listed in the European Pharmacopoeia (Ph. Eur. 11.1.2023).

([2]) 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.

([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, ELI: http://data.europa.eu/eli/reg/2009/152/oj).

([4]) Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/429/oj).

([5]) 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, ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj).