EN

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]-	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,	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for*	50 µg narasin/kg of all wet tissues Diclazuril: Commission Regulation (EU) No 37/2010 ([4])

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

			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; $C_{43}H_{72}O_{11}$; CAS number: 55134-13-9: ≥ 85%. * narasin B, D and I. - 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).					premixtures and compound feed: 'Dangerous for equines, turkeys and rabbits. This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances, including tiamulin, is contra-indicated.' 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 ([3]). 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 publica-tion]*	

([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 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).

			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. 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. For the determination of diclazuril in compound feed: - High Performance Liquid Chromatography coupled with photometric detection (HPLC-UV) – Commission Regulation (EC) No 152/2009 or - High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-					the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.		

			MS/MS) – EN 17299. For the determination of narasin in tissues: High Performance Liquid Chromatography coupled with tandem mass spectrometry – AOAC 2011.24.							