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COMMISSION REGULATION (EU) No 885/2010

of 7 October 2010

concerning the authorisation of the preparation of narasin and nicarbazin as a feed additive for chickens for fattening (holder of authorisation Eli Lilly and Company Ltd) and amending Regulation (EC) No 2430/1999

(Text with EEA relevance)

(OJ L 265, 8.10.2010, p. 5)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2018/1957 of 11 December 2018	L 315	23	12.12.2018

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COMMISSION REGULATION (EU) No 885/2010

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(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

In Annex I to Regulation (EC) No 2430/1999, the entry under the registration number of additive E 772, concerning Narasin 80 g/kg — Nicarbazin 80 g/kg (Maxiban G160), is deleted.

Premixture and compound feed containing the feed additive labelled in accordance with Regulation (EC) No 2430/1999 may continue to be placed on the market and remain on the market and used until stocks are exhausted.

Article 3

This Regulation shall enter into force on the 20th day following 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	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										
5 1 772	►**M1** Elanco GmbH ◄	Narasin 80 g activity/kg Nicarbazin 80 g/kg (Maxiban G160)	*Additive composition* Narasin: 80 g activity/kg Nicarbazin: 80 g/kg (Ratio 1:1) Vegetal or mineral oil: 10-30 g/kg Vermiculite: 0-20 g/kg Micro tracer red: ►**M1** 4-11 g/kg ◄ Corn cob grits or rice hulls qs 1 kg *Active substance* 1. Narasin, $C_{43}H_{72}O_{11}$ CAS number: 55134-13-9 polyether monocarboxylic acid produced by *Streptomyces aureofaciens* (NRRL 8092), in granular form Narasin A activity: ≥ 85 %	Chickens for fattening	—	40 mg Narasin 40 mg Nicarbazin	50 mg Narasin 50 mg Nicarbazin	1. Indicate in the instructions for use: ‘Dangerous for equine species, turkeys and rabbits’ ‘This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances can be contraindicated’. 2. The additive shall be incorporated in compound feed in form of a premixture. 3. The preparation of narasin and nicarbazin shall not be mixed with other coccidiostats. 4. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation.	28 October 2020	50 µg of narasin/kg for fresh liver, muscle, kidney and skin/fat. 15 000 µg of dinitrocarbanilide (DNC)/kg of fresh liver; 6 000 µg of DNC/kg of fresh kidney; 4 000 µg of DNC/kg for fresh muscle and fresh skin/fat.

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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	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 %				
			2. Nicarbazin, $C_{19}H_{18}N_6O_6$. CAS number: 330-95-0 equimolecular complex of 1,3-bis(4-nitrophenyl) urea and 4,6 dimethyl-pyrimidin-2-ol, in granular form Related impurities: p-nitroaniline: ≤ 0,3 % *Analytical methods* (1) For the determination of narasin: reversed-phase high performance liquid chromatography (HPLC) using post-column derivatisation with vanillin and detection at 520 nm - ISO 14183:2005. For determination of nicarbazin: high performance liquid chromatography method and ultraviolet detection (HPLC-UV) spectrometry (LC-MS/MS)					5. From 28 October 2013 the p-nitroaniline content shall be ≤ 0,1 %. 6. For safety: breathing protection shall be used during handling.		

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives