COMMISSION IMPLEMENTING REGULATION (EU) 2020/994

of 9 July 2020

concerning the authorisation of monensin and nicarbazin (Monimax) as a feed additive for turkeys for fattening, chickens for fattening and chickens reared for laying (holder of 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 monensin and nicarbazin (Monimax). 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 monensin and nicarbazin (Monimax) as a feed additive for turkeys for fattening, chickens for fattening and chickens reared for laying to be classified in the additive category 'coccidiostats and histomonostats'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 November 2017 ([2]), 2 October 2018 ([3]) and 7 October 2019 ([4]) that, under the proposed conditions of use, monensin and nicarbazin (Monimax) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive presents a hazard by inhalation, and may act as dermal toxicant. No data are available for the eye irritation potential. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive is considered efficacious to control coccidiosis in turkeys and chickens for fattening and chickens reared for laying. It also concluded that a post-market monitoring plan to monitor the *Eimeria* spp. resistance should be undertaken. 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 monensin and nicarbazin (Monimax) 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 additive 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

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2017;15(12):5094.
([3]) *EFSA Journal* 2018;16(11):5459.
([4]) *EFSA Journal* 2019;17(11):5888.

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*.

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

Done at Brussels, 9 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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										
51776	Huvepharma NV.	Monensin 80 g/kg Nicarbazin 80 g/kg (Monimax)	**Additive composition:** Preparation of: Monensin (as monensin sodium) 80 g/kg (monensin A ≥ 90%, monensin A +B≥ 95%, monensin C 0.2-0.3%) Nicarbazin 80 g/kg (Ratio 1:1) Starch: 15 g/kg. Wheat meal: 580 g/kg. Calcium carbonate: q.s. 1000 g Granular form **Characterisation of the active substance:** **Monensin as monensin sodium technical substance** (activity ≥ 27%) CAS number 22373-78-0 produced by *Streptomyces cinnamonensis* 28682 BCCM/LMG S-19095) consisting of: — monensin A sodium: sodium (2-[5-ethyltetrahydro-5-[tetrahydro-3-methyl-5-[tetrahydro-6-hydroxy-6-(hydroxymethyl)-3,5-dimethyl-2H-pyran-2-yl]-2-furyl]-2-furyl]-9-hydroxy-β-methoxy-α,γ,2,8-tetramethyl-1,6-dioxaspiro-[4.5]decane-7-butyric acid; $C_{36}H_{61}NaO_{11}$, — monensin B sodium: sodium 4-(9-hydroxy-2-(5'-(6-hydroxy-	Chickens for fattening		40 mg monensin sodium 40 mg nicarbazin	50 mg monensin sodium 50 mg nicarbazin	1. The additive shall be incorporated in compound feed in the form of a premixture. 2. The additive shall not be mixed with other coccidiostats. 3. Indicate in the instructions for use: 'Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances'. 4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: — resistance to bacteria and Eimeria spp.; 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational	30.7.2030	25 µg monensin sodium/kg of wet skin + fat; 8 µg monensin sodium/kg of wet liver, kidney and muscle. 15 000 µg of DNC/kg of wet liver; 6 000 µg of DNC/kg of wet kidney; 4 000 µg of DNC/kg for wet muscle and wet skin/fat.
				Turkeys for fattening	16 weeks					
				Chickens reared for laying	16 weeks					

			6-(hydroxymethyl)-3,5-dimethyltetrahydro-2H-pyran-2-yl)-2,3'-dimethyloctahydro-[2,2'-bifuran]-5-yl)-2,8-dimethyl-1,6-dioxaspiro[4.5]decan-7-yl)-3-methoxy-2-methylpentanoate; $C_{35}H_{59}NaO_{11}$, — monensin C sodium: sodium 2-ethyl-4-(2-(2-ethyl-5'-(6-hydroxy-6-(hydroxymethyl)-3,5-dimethyltetrahydro-2H-pyran-2-yl)-3'-methyloctahydro-[2,2'-bifuran]-5-yl)-9-hydroxy-2,8-dimethyl-1,6-dioxaspiro[4.5]decan-7-yl)-3-methoxypentanoate,; $C_{37}H_{63}NaO_{11}$ **Nicarbazin** $C_{19}H_{18}N_6O_6$. CAS number: 330-95-0 equimolecular complex of: — 4,4-dinitrocarbanilide (DNC) (67.4-73%) $C_{13}H_{10}N_4O_5$, — 2-hydroxy-4,6-dimethylpyrimidine (HDP) (27-30%) — free HDP ≤ 2.5%. $C_6H_8N_2O$ Related impurities: — p-nitro- aniline (PNA): ≤ 0,1 % — methyl(4-nitrophenyl) carbamate (M4NPC): ≤ 0.4 %.					measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye, dermal and breathing protection.		
			Analytical method [1] Quantification of monensin in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled to Visible detection (HPLC-VIS)							

[1] 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

			Quantification of monensin in premixtures and feedingstuffs: High Performance Liquid Chromatography using post-column derivatisation coupled to Visible detection (HPLC-VIS) - EN ISO 14183 Quantification of nicarbazin in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled to Ultra-Violet detection (HPLC-UV) Quantification of nicarbazin in premixtures and feedingstuffs: High Performance Liquid Chromatography using post-column derivatisation coupled to Ultra-Violet detection (HPLC-UV) - EN ISO 15782 For the quantification of monensin sodium and nicarbazin in tissues: Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods complying with the requirements set by Commission Decision 2002/657/EC							