

EN
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										
51776	Huvepharma NV.	Monensin 80 g/kg	Additive composition: Preparation of monensin (as monensin sodium) 80 g/kg (monensin A ≥ 90%, monensin A+B≥ 95%, monensin C ≥ 0.2-0.3%) Nicarbazine 80 g/kg (Ratio 1:1) Starch:15 g/kg. Wheat meal: 580g/kg. Calcium carbonate: q.s. 1000 g Granular form ----- Characterisation of the active substance:	Turkeys for fattening		40 mg monensin	50 mg monensin	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	[10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the	25 µg monensin/kg of wet skin + fat.
		Nicarbazine 80 g/kg (Monimax)		Chickens for fattening		40 mg nicarbazine	50 mg nicarbazine			8 µg monensin/kg of wet
				Chickens reared for laying						liver, kidney and muscle.
										15 000 µg of DNC/kg of fresh liver;

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			<p>Monensin as monensin sodium technical substance (activity ≥ 27%) CAS number 22373-78-0 produced by <i>Streptomyces cinnamonensis</i> 28682 BCCM/LMG S-19095) consisting of: monensin A 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; C₃₆H₆₁NaO₁₁, - monensin B sodium: sodium 4-(9-hydroxy-2-(5'-(6-hydroxy-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]decane-7-yl)-3-methoxy-2-methylpentanoate; C₃₅H₅₉NaO₁₁, - 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]decane-7-yl)-3-methoxypentanoate,; C₃₇H₆₃NaO₁₁</p> <p>Nicarbazin, C₁₉H₁₈N₆O₆. CAS number: 330-95-0 equimolecular complex of: - 4,4-dinitrocarbanilide (DNC) (67.4-73%) C₁₃H₁₀N₄O₅,</p>				<p>administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances'</p> <p>4. Post-market monitoring programmes shall be carried out by the holder of authorisation for:</p> <ul style="list-style-type: none"> - resistance to bacteria and <i>Eimeria</i> spp.; <p>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational 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,</p>	<p>publica- tion]</p>	<p>6 000 µg of DNC/kg of fresh kidney;</p> <p>4 000 µg of DNC/kg for fresh muscle and fresh skin/fat.</p>
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		<p>- 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 %.</p> <p>-----</p> <p>Analytical method¹ Quantification of monensin in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled to Visible detection (HPLC-VIS)</p> <p>Quantification of monensin in premixtures and feedingstuffs: High Performance Liquid Chromatography using post-column derivatisation coupled to Visible detection (HPLC-VIS) - EN ISO 14183</p> <p>Quantification of nicarbazine in the feed additive: High Performance Liquid Chromatography using post-column derivatisation coupled to UltraViolet detection (HPLC-UV)</p> <p>Quantification of nicarbazine in premixtures and feedingstuffs:</p>					dermal and breathing protection.		
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¹ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/irc/en/eurl/feed-additives/evaluation-reports>

			<p>High Performance Liquid Chromatography using post-column derivatisation coupled to UltraViolet detection (HPLC-UV) - EN ISO 15782</p> <p>For the quantification of monensin sodium and nicarbazin in tissues:</p> <p>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</p>								
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