

EN

ANNEX

Identi- fication 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 author isation	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										
51701	Huvepharma N.V.	Monensin sodium (Coxidin)	Additive composition Preparation of monensin sodium equivalent to monensin activity ¹ : 23,7-26,2 % Forms with: - Wheat bran: q.s. or - Calcium carbonate q.s. Solid forms. Characterisation of the active substance Monensin sodium (sodium salt of polyether monocarboxylic acid), 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-	Chickens for fattening	-	100	120	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. Monensin sodium shall not be mixed with other coccidiostats. 4. Indicate in the instructions for use: ‘Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with	[10 years from the date of entry into force of this Regula- tion. To be complet ed by the Service responsi ble for the publica- tion]	25 µg monensin sodium/kg of wet skin + fat 8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle
				Chickens reared for laying	16 weeks	100	120			
				Turkeys for fattening Turkeys reared for reproduction	16 weeks	60	100			

⁽¹⁾ The concentration of monensin sodium is expressed as monensin activity which includes the relative biopotency in terms of ‘monensin activity’ of the different monensin variants.

		<p>tetramethyl-1,6-dioxaspiro-[4.5]decane-7-butyric acid; $C_{36}H_{61}NaO_{11}$;</p> <p>- 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]decan-7-yl)-3-methoxy-2-methylpentanoate; $C_{35}H_{59}NaO_{11}$;</p> <p>- 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; $C_{37}H_{63}NaO_{11}$.</p> <p>From 'monensin sodium technical substance', composed of:</p> <p>- Monensin sodium equivalent to monensin activity: 32-42 %;</p> <p>- Perlite: 15-20 %;</p> <p>- Dried exhausted fermentation substrate: 38-53 %;</p> <p>- CAS number: 22373-78-0;</p> <p>- Produced by fermentation with <i>Streptomyces</i> sp. LMG S-19095.</p> <p>Factor composition:</p> <p>- Monensin A: ≥ 90 %</p> <p>- Monensin A + B: ≥ 95 %</p> <p>- Monensin C: 0,2-0,3 %</p>					<p>tiamulin and monitor for possible adverse reactions, when used concurrently with other medicinal substances'.</p> <p>5. A post-market monitoring program on the resistance of <i>Eimeria</i> spp. and bacteria to monensin sodium shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 ⁽³⁾. That post-market monitoring program shall include, as of [5 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication], EU wide field monitoring of resistance of <i>Eimeria</i> to monensin sodium and in-vitro screenings or anticoccidial sensitivity tests for single <i>Eimeria</i> strains collected from different chicken farms across the EU for which an indication of resistance is identified. It shall also include, as of [7 years from the date of entry into force of this Regulation.</p>		
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			<p>Analytical method ⁽²⁾</p> <p>For the determination of monensin sodium in the feed additive: high performance liquid chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis).</p> <p>For the determination of monensin sodium in premixtures: high performance liquid chromatography using post-column derivatisation coupled with photometric detection (HPLC-PCD-UV-Vis) – EN ISO 14183.</p> <p>For the determination of monensin sodium in compound feed:</p> <ul style="list-style-type: none"> - 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. <p>For the determination of monensin sodium in tissues: high performance liquid chromatography coupled with tandem mass spectrometry (HPLC-</p>					<p><i>To be completed by the Service responsible for the publication]</i> at the latest, anticoccidial sensitivity tests (mixed infection) in chickens and turkeys covering a broad range of <i>Eimeria</i> strains originating from EU locations in which indications of resistance have been identified and implemented consistently across the EU.</p> <p>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 and eye protective equipment, and also with skin protective equipment for the form with calcium carbonate.</p>		
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⁽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>).

⁽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.

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