

EN
ANNEX

Identi- fication number of the additive	Name of the holder of authorisati on	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 authoris ation	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%				
Category: coccidiostats and histomonostats										
51757	Elanco GmbH	Monensin sodium (Elancoban G200)	Additive composition Preparation of: - monensin sodium (dried fermentation product): 185-215 g/kg - food grade mineral oil: 10-25 g/kg Forms with: - Rice hulls: q.s. 1 kg. or - granular limestone: q.s. 1 kg. Solid forms. Characterisation of the active substance Monensin sodium (sodium salt of polyether monocarboxylic acid monensin), 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;	Chickens for fattening	-	100	100	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. Use prohibited at least one day before slaughter. 3. The additive shall be incorporated in compound feed in the form of a premixture. 4. Monensin sodium shall not be used simultaneously with other coccidiostats. 5. Indicate in the directions for use of the additive, premixtures and related feed: ‘Dangerous for equines. This feed contains an ionophore: simultaneous use with certain medicinal	[10 years from the date of entry into force of this Regula- tion. To be completed by the Service responsi- ble for the publica- tion]	25 µg monensin sodium/kg wet skin + fat 8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle
				Chickens reared for laying	16 weeks	100	100			
				Turkeys for fattening Turkeys reared for reproduction	16 weeks	60	100			

		C₃₆H₆₁NaO₁₁; - Monensin B sodium: C₃₅H₅₉NaO₁₁; - Monensin C sodium: C₃₇H₆₃NaO₁₁; - Monensin D sodium: C₃₇H₆₃NaO₁₁; - Monensin E sodium: C₃₆H₆₁NaO₁₁; CAS number: 22373-78-0; Produced by fermentation with <i>Streptomyces</i> sp. NRRL B-67924. Factor composition: - Monensin A: 86,4-90,3 % - Monensin B: 5,7-9,3 % - Monensin A+B: 94,8-97,7 % - Monensin C+D: 0,5-1,3 % - Monensin E: 1,4-3,6 % Analytical method ⁽¹⁾ 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). 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. For the determination of monensin				substances, including tiamulin, is contra-indicated.’ 6. A post-market monitoring program on the resistance of <i>Eimeria</i> spp. to monensin sodium shall be planned and executed by the holder of authorisation in accordance with Commission Regulation (EC) No 429/2008 ⁽²⁾. That post-market monitoring program shall include, as of <i>[5 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</i>, 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 <i>[7 years from the date of</i>		
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⁽¹⁾ 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.

⁽²⁾ 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).

			sodium in compound feeds: – 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 monensin sodium in tissues: High performance liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS).					<i>entry into force of this Regulation. 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. 7. 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.		
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