

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										
51765	Elanco GmbH	Narasin 100 g/kg (Monteban G100)	Additive composition Preparation of - narasin: 95,0-107,5 g/kg - food grade mineral oil: 10-25 g/kg - rice hulls qs 1 kg. Solid form. Characterisation of the active substance Narasin granulated containing: - Narasin: ≥ 100 g/kg, including: * narasin A: ((2 <i>R</i>)-2-{(2 <i>R</i> ,3 <i>S</i> ,5 <i>S</i> ,6 <i>R</i>)-6- [(2 <i>S</i> ,3 <i>S</i> ,4 <i>S</i> ,6 <i>R</i>)-6- {(2 <i>S</i> ,5 <i>S</i> ,7 <i>R</i> ,9 <i>S</i> ,10 <i>S</i> ,12 <i>R</i> ,15 <i>R</i>)-2- [(2 <i>R</i> ,5 <i>R</i> ,6 <i>S</i>)-5-ethyl-5-hydroxy-6- methyltetrahydro-2 <i>H</i> -pyran-2-yl]-15- hydroxy-2,10,12-trimethyl-1,6,8- trioxadispiro[4.1.5 ⁷ .3 ⁵]pentadec-13-en- 9-yl}-3-hydroxy-4-methyl-5-oxooctan- 2-yl]-3,5-dimethyltetrahydro-2 <i>H</i> -pyran- 2-yl}butanoic acid; C43H72O11; CAS number: 55134-13-9: ≥ 90%. * narasin B, D and I. - Fermentation mass: 28%. - Dipotassium hydrogen phosphate: 6%. - Montmorillonite clay: 53%.	Chickens for fattening	-	60	70	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. The additive shall not be used simultaneously with other coccidiostats. 4. Indicate in the directions for use of the additive, premixtures and compound feed: ‘Dangerous for equines, turkeys and rabbits. This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances, including tiamulin, is contra-	[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]	50 µg narasin/kg of all wet tissues

			<p>Produced by fermentation with <i>Streptomyces</i> spp. NRRL B-67771.</p> <p>Analytical methods ⁽¹⁾</p> <p>For the determination of narasin 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 narasin in the 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 narasin 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 narasin in tissues: High Performance Liquid Chromatography coupled with tandem mass spectrometry (LC-MS/MS).</p>				<p>indicated.’</p> <p>5. A post-market monitoring programme on the resistance of <i>Eimeria</i> spp. to narasin shall be planned and executed by the holder of authorisation, in accordance with Commission Regulation (EC) No 429/2008 ⁽²⁾.</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, eye and skin protective equipment.</p>		
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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, ELI: <http://data.europa.eu/eli/reg/2008/429/oj>).