

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 %				
<i>Coccidiostats and histomonostats</i>										
5 1 772	Eli Lilly and Company Ltd	Narasin 80 g activity/kg Nicarbazin 80 g/kg (Maxiban G160)	<p><i>Additive composition</i></p> <p>Narasin: 80 g activity/kg</p> <p>Nicarbazin: 80 g/kg</p> <p>(Ratio 1:1)</p> <p>Vegetal or mineral oil: 10-30 g/kg</p> <p>Vermiculite: 0-20 g/kg</p> <p>Micro tracer red: 11 g/kg</p> <p>Corn cob grits or rice hulls qs 1 kg</p> <p><i>Active substance</i></p> <p>1. Narasin, C₄₃H₇₂O₁₁</p> <p>CAS number: 55134-13-9</p> <p>polyether monocarboxylic acid produced by <i>Streptomyces aureofaciens</i> (NRRL 8092), in granular form</p> <p>Narasin A activity: ≥ 85 %</p> <p>2. Nicarbazin, C₁₉H₁₈N₆O₆.</p> <p>CAS number: 330-95-0</p> <p>equimolecular complex of 1,3-bis(4-nitrophenyl) urea and 4,6 dimethylpyrimidin-2-ol, in granular form</p> <p>Related impurities: p-nitroaniline: ≤ 0,3 %</p>	Chickens for fattening	—	40 mg Narasin	50 mg Narasin	<p>1. Indicate in the instructions for use: 'Dangerous for equine species, turkeys and rabbits'</p> <p>'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances can be contraindicated'.</p> <p>2. The additive shall be incorporated in compound feed in form of a premixture.</p> <p>3. The preparation of narasin and nicarbazin shall not be mixed with other coccidiostats.</p> <p>4. A post-market monitoring program on the resistance to bacteria and <i>Eimeria</i> spp. shall be planned and executed by the holder of authorisation.</p> <p>5. From 28 October 2013 the p-nitroaniline content shall be ≤ 0,1 %.</p> <p>6. For safety: breathing protection shall be used during handling.</p>	28 October 2020	<p>50 µg of narasin/kg for fresh liver, muscle, kidney and skin/fat.</p> <p>15 000 µg of dinitrocarbanilide (DNC)/kg of fresh liver;</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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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			<p><i>Analytical methods</i> ⁽¹⁾</p> <p>For the determination of narasin: reversed-phase high performance liquid chromatography (HPLC) using post-column derivatisation with vanillin and detection at 520 nm - ISO 14183:2005.</p> <p>For determination of nicarbazin: high performance liquid chromatography method and ultraviolet detection (HPLC-UV) spectrometry (LC-MS/MS)</p>							

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives