

Identification number of the additive	Name of the holder of authorisation	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 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 %	mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			Related impurities: Maduramicin ammonium β : $\leq 1\%$							
			Analytical method⁽¹⁾ For the determination of maduramicin ammonium alpha in the additive, premixtures and feed-stuffs: reversed-phased high performance liquid chromatography (HPLC) using post-column derivatization with vanillin and detection at 520nm-EN 15781:2009. For the determination of residues of maduramicin ammonium alpha in liver and muscle: reversed-phased high performance liquid chromatography (HPLC) coupled to tandem mass spectrometry.							

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives

ANNEX

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Coccidiostats and histomonostats										
5 1 770	Alpharma (Belgium) BVBA	Maduramicin ammonium alpha 10 g/kg (Cygro 10 G)	Additive Composition Maduramicin ammonium alpha: 10 g/kg Carboxymethylcellulose sodium: 20 g/kg Calcium sulphate dihydrate: 970 g/kg Active substance Maduramicin ammonium alpha C ₄₇ H ₈₃ O ₁₇ N CAS number: 84878-61-5 (2R, 3S, 4S, 5R, 6S)-6{[1R)-1-[[2S,5R,7S,8R,9S)-2-[[2S,2R,3'S,5R,5 'R)-3'-[{[2,6-dideoxy-3,4-di- O-methyl-β-L-arabinohexopyra nosyl]oxy]-octahydro-2- methyl-5'-[(2S,3S,5R,6S)- tetrahydro-6-hydroxy-3,5,6- trimethyl-2H-pyran- 2-yl][2,2'-bifuran]-5-yl]-9- hydroxy-2,8-dimethyl- 1,6dioxaspiro[4.5]dec-7- yl]ethyl}[tetrahydro- 2-hydroxy-4,5- dimethoxy-3- methyl-3H-pyran-2-acetic acid, monoammonium salt produced by a fermentation process by the strain <i>Actinomadura</i> <i>yumaensis</i> NRRL 12515; ≥ 90 %.	Chickens for fattening	—	5	6	<p>1. The additive shall be incorporated in compound feed in form of a premixture.</p> <p>2. Maduramicin ammonium alpha shall not be mixed with other coccidiostats.</p> <p>3. Indicate in the instructions for use: 'Dangerous for equines'. This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated.</p> <p>4. For safety: breathing protection, glasses and gloves shall be used during handling.</p> <p>5. A post-market monitoring program on the resistance to <i>Eimeria</i> spp. shall be planned and executed by the holder of authorisation.</p> <p>6. The use is prohibited at least 3 days before slaughter</p>	10 May 2021	150 µg of maduramicin ammonium/kg of fresh liver, skin and fat; 100 µg of maduramicin ammonium/kg of fresh kidney; 30 µg of maduramicin ammonium/kg of fresh muscle.