

## ANNEX II

The Annex to Regulation (EC) No 1800/2004 is replaced by the following:

## ANNEX

Registration number of the additive	Name and the registration number of the person responsible for putting additive into circulation	Additive (Trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedstuff	mg of active substance/kg of complete feedstuff			
<b>Coccidiostats and other medicinal substances</b>										
E 758	Alpharma Belgium BVBA	Robenidine hydrochloride 66 g/kg (Cycostat 66G)	<p><i>Additive composition</i></p> <p>Robenidine hydrochloride: 66 g/kg Lignosulfonate: 40 g/kg Calcium sulphate dihydrate: 894 g/kg</p> <p><i>Active substance</i></p> <p>Robenidine hydrochloride, C<sub>15</sub>H<sub>13</sub>Cl<sub>2</sub>N<sub>5</sub>·HCl, 1,3-bis [(p-chlorobenzylidene) amino]-guanidine hydrochloride CAS number: 25875-50-7, Related impurities: N,N'-Tris[(p-Cl-benzylidene)amino]guanidine (TRIS): ≤ 0,5 % Bis-[4-(Cl-benzylidene)hydrazine (AZIN): ≤ 0,5 %</p>	Chickens for fattening	—	30	36	36	Use is prohibited at least 5 days before slaughter.	29 October 2014
				Turkeys		30	36	36	Use is prohibited at least 5 days before slaughter.	29 October 2014

## ANNEX I

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 feedstuff with a moisture content of 12 %						
<b>Coccidiostats and histomonostats</b>												
5 1 758	Alpharma Belgium BVBA	Robenidone hydrochloride 66g/kg (Cycostat 66G)	<p><i>Additive composition</i></p> <p>Robenidone hydrochloride: 66 g/kg</p> <p>Lignosulfonate: 40 g/kg</p> <p>Calcium sulphate dihydrate: 894 g/kg</p> <p><i>Active substance</i></p> <p>Robenidone hydrochloride, <math>C_{15}H_{13}Cl_2N_5 \cdot HCl</math>, CAS number: 25875-50-7, 1,3-bis [(p-chlorobenzylidene) amino]guanidine hydrochloride: &gt; 97 %</p> <p>Related impurities:</p> <p>N,N'-Tris[(p-Cl-benzylidene) amino]guanidine (TRIS): <math>\leq 0,5 \%</math></p> <p>Bis-4[4-Cl-benzylidene]hydrazine (AZIN): <math>\leq 0,5 \%</math></p> <p><i>Analytical methods (1)</i></p> <p>Determination of robenidone hydrochloride in feed: reverse phase high performance liquid chromatography coupled to ultraviolet spectrometry (HPLC/UV) in accordance with Method E in Annex IV to Commission Regulation (EC) No 152/2009 (2).</p>	Rabbits for breeding Rabbits for fattening	—	50	66	66	<p>1. The additive shall be incorporated in compound feed in the form of a pre-mixture.</p> <p>2. Robenidone hydrochloride shall not be mixed with other coccidiostats.</p> <p>3. For safety: breathing protection, glasses and gloves shall be used during handling.</p> <p>4. 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>5. Use is prohibited at least 5 days before slaughter.</p>	21 June 2021	200 µg/kg wet weight for liver and kidney 100 µg /kg wet weight for all other tissues	

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory: [http://irmm.jrc.ec.europa.eu/EURLs/EURL\\_feed\\_additives/Pages/index.aspx](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)

(2) OJ L 54, 26.2.2009, p. 1.