

## ANNEX

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 %				
<b>Coccidiostats and histomonostats</b>										
5 1 771	Janssen Pharmaceutica NV	Diclazuril 0,5 g/ 100 g  (Clinacox 0,5 %)	<p><i>Additive composition</i></p> <p>Diclazuril: 0,50 g/100 g.</p> <p>Protein-poor soybean meal: 99,25 g/100 g</p> <p>Polyvidone K 30: 0,20 g/100 g</p> <p>Sodium hydroxide: 0,05 g/100 g</p> <p><i>Characterisation of the active substance</i></p> <p>Diclazuril, C<sub>17</sub>H<sub>9</sub>Cl<sub>3</sub>N<sub>4</sub>O<sub>2</sub>, (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2</p> <p>Related impurities:</p> <p>Degradation compound (R064318): ≤ 0,1 %</p> <p>Other related impurities (T001434, R066891, R068610, R070156, R070016): ≤ 0,5 % individually</p> <p>Total impurities: ≤ 1,5 %</p>	Chickens for fattening	—	1	1	<p>1. The additive shall be incorporated in compound feed in form of a premixture.</p> <p>2. Diclazuril 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 bacteria and <i>Eimeria</i> spp. shall be planned and executed by the holder of authorisation.</p>	23 December 2020	<p>1 500 µg diclazuril/kg of wet liver</p> <p>1 000 µg diclazuril/kg of wet kidney</p> <p>500 µg diclazuril/kg of wet muscle</p> <p>500 µg diclazuril/kg of wet skin/fat</p>

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						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			<p><i>Analytical method</i> <sup>(1)</sup></p> <p>For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Regulation (EC) No 152/2009)</p> <p>For determination of diclazuril in poultry tissues: HPLC coupled to triple quadrupole mass spectrometer (MS/MS) using one precursor ion and two product ions.</p>							

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