

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 %				
Coccidiostats and histomonostats										
51771	Eli Lilly and Company Ltd	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, C₁₇H₉Cl₃N₄O₂, (±)-4-chloro-phenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetoneitrile,</p> <p>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> <p><i>Analytical method</i> ⁽¹⁾</p> <p>For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280 nm (Commission Regulation (EC) No 152/2009 ⁽²⁾).</p>	Chickens reared for laying	16 weeks	1	1	<ol style="list-style-type: none"> The additive shall be incorporated in compound feed in the form of a premixture. Diclazuril shall not be mixed with other coccidiostats. For safety: breathing protection, glasses and gloves shall be used during handling. A post-market monitoring programme concerning the resistance to bacteria and <i>Eimeria</i> spp. shall be carried out by the holder of authorisation. 	2 August 2023	Commission Regulation (EU) No 37/2010 ⁽³⁾