

## 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 feedstuff with a moisture content of 12 % |   |                 |   |                                |  |
| <b>Coccidiostats and histomonostats</b> |                                     |   |  |                               |             |   |   |                 |   |                                |  |
| 5 1 771                                 | Janssen Pharmaceutica N.V.          | Diclazuril 0,5 g/100 g (Clinacox 0,5 %) | <p><i>Additive composition</i><br/> Diclazuril: 0,50 g/100 g;<br/> Protein-poor soybean meal: 99,25 g/100 g<br/> Polyvidone K 30: 0,20 g/100 g<br/> Sodium hydroxide: 0,05 g/100 g</p> <p><i>Characterisation of the active substance</i><br/> Diclazuril, C<sub>17</sub>H<sub>9</sub>Cl<sub>3</sub>N<sub>3</sub>O<sub>2</sub>,<br/> (±)-4-chlorophenyl[2,6-dichloro-4-(2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetoneitrile,<br/> CAS number: 101831-37-2</p> <p>Related impurities:<br/> Degradation compound (R064318): ≤ 0,1 %<br/> Other related impurities (T001434, R066891, R068610, R070156, R070016): ≤ 0,5 % individually<br/> Total impurities: ≤ 1,5 %</p> <p><i>Analytical method (1)</i><br/> For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280 nm (Regulation (EC) No 152/2009)<br/> 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> | Guinea fowls                  | —           | 1   | 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. The holder of the authorisation shall carry out a post-market monitoring programme on the resistance to bacteria and <i>Eimeria</i> spp.</p> | 16 March 2021                  | <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> |

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