Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 495/2011, ANNEX. (See end of Document for details)

ANNEX

'ANNEXDetails of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/ EURLs/EURL feed additives/Pages/index.aspx'Identification number additiveName of the holder of authorisationAdditive(Trade name)Composition, chemical formula, description, analytical methodSpecies or category of animalMaximum ageMinimum contentMaximum contentOther provisionsEnd of period of authorisationProvisional maximum residue limits (MRLs) in the relevant foodstuffs of animal originmg of active substance/kg of complete feedingstuff with a moisture content of 12 %Coccidiostats and histomonostats51701Huvepharma NV BelgiumMonensin sodium(Coxidin)Additive compositionMonensin sodium technical substance equivalent to monensin activity: 25 %Perlite: 15 – 20 %Wheat bran 55 - 60 %Active substanceC36H61O11NaSodium salt of polyether monocarboxylic acid produced by Streptomyces cinnamonensis 28682, LMG S-19095 in powder formFactor compositionMonensin A: not less than 90 %Monensin A + B: not less than 95 %Monensin C: 0,2 – 0,3 %Analytical methodMethod for determination of the active substance: high performance liquid chromatography (HPLC) with post-column derivatisation and UV detection ($\lambda = 520$ nm)Chickens for fattening—1001251. Use prohibited at least 1 day before slaughter.

2.

The additive shall be incorporated in compound feedingstuffs in form a premixture. 3.Maximum permitted dose of monensin sodium in complementary feedingstuffs:

- 625 mg/kg for chickens for fattening,
- 500 mg/kg for turkeys.

4.

Monensin sodium shall not be mixed with other coccidiostats.

5.Indicate in the instructions for use:

Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.

6.

Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation in the premise, wear suitable respiratory equipments. 6.2.201725 µg monensin sodium/kg of wet skin + fat8 µg monensin sodium/kg of wet liver, wet kidney and wet muscleTurkeys16 weeks6010051701Huvepharma NV BelgiumMonensin sodium(Coxidin)Additive compositionMonensin sodium technical substance equivalent to monensin activity: 25 %Perlite: 15 – 20 %Calcium Carbonate: qs. 100 %Active substanceC36H61O11NaSodium salt of polyether monocarboxylic acid produced by Streptomyces cinnamonensis 28682, LMG S-19095 in powder formFactor compositionMonensin A: not less than 90 %Monensin A + B: not less than 95 %Monensin C: 0,2 – 0,3 %Analytical methodMethod for determination of the active substance: high-performance liquid chromatography (HPLC) with post-column derivatisation and UV-VIS detection (EN ISO standard method 14183:2008)Chickens for fattening—1001251.

Use prohibited at least 1 day before slaughter.

2.

The additive shall be incorporated in compound feedingstuffs in form of a granulated premixture.

3.

Monensin sodium shall not be mixed with other coccidiostats.

4. Indicate in the instructions for use:

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 495/2011, ANNEX. (See end of Document for details)

Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.

5

Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation in the premise, wear suitable respiratory equipments. 10.6.202125 µg monensin sodium/kg of wet skin + fat8 µg monensin sodium/kg of wet liver, wet kidney and wet muscleTurkeys16 weeks60100

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 495/2011, ANNEX.