

COMMISSION IMPLEMENTING REGULATION (EU) No 495/2011
of 20 May 2011
amending Regulation (EC) No 109/2007 as regards the composition of the feed additive monensin sodium

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 13(3) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the possibility to modify the authorisation of a feed additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority (the Authority).
- (2) The use of monensin sodium, belonging to the group of coccidiostats and histomonostats, was authorised for 10 years as a feed additive for use on chickens for fattening and turkeys by Commission Regulation (EC) No 109/2007⁽²⁾.
- (3) The holder of the authorisation submitted an application for a modification of the authorisation of monensin sodium as regards an additional composition of that feed additive. Relevant data were submitted to support this request.

(4) The Authority concluded in its opinion of 1 February 2011⁽³⁾ that the use of this new formulation of the additive on chickens for fattening and turkeys does not raise any additional concerns for animal health, human health or the environment and that it is effective in controlling coccidiosis. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(5) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(6) Regulation (EC) No 109/2007 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 109/2007 is replaced by the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 May 2011.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 31, 6.2.2007, p. 6.

⁽³⁾ EFSA Journal 2011; 9(2):2009.

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	Provisional 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										
51701	Huvepharma NV Belgium	Monensin sodium (Coxidin)	<p><i>Additive composition</i></p> <p>Monensin sodium technical substance equivalent to monensin activity: 25 %</p> <p>Perlite: 15 – 20 %</p> <p>Wheat bran 55 – 60 %</p> <p><i>Active substance</i></p> <p>$C_{36}H_{61}O_{11}Na$</p> <p>Sodium salt of polyether monocarboxylic acid produced by <i>Streptomyces cinnamonensis</i> 28682, LMG S-19095 in powder form</p> <p><i>Factor composition</i></p> <p>Monensin A: not less than 90 %</p> <p>Monensin A + B: not less than 95 %</p> <p>Monensin C: 0,2 – 0,3 %</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Method for determination of the active substance: high performance liquid chromatography (HPLC) with post-column derivatisation and UV detection ($\lambda = 520nm$)</p>	Chickens for fattening	—	100	125	<p>1. Use prohibited at least 1 day before slaughter.</p> <p>2. The additive shall be incorporated in compound feedingstuffs in form a premixture.</p> <p>3. Maximum permitted dose of monensin sodium in complementary feedingstuffs:</p> <p>— 625 mg/kg for chickens for fattening,</p> <p>— 500 mg/kg for turkeys.</p> <p>4. Monensin sodium shall not be mixed with other coccidiostats.</p> <p>5. Indicate in the instructions for use:</p> <p>“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”.</p> <p>6. Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation in the premise, wear suitable respiratory equipments.</p>	6.2.2017	<p>25 µg monensin sodium/kg of wet skin + fat</p> <p>8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle</p>
				Turkeys	16 weeks	60	100			

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	Provisional 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 %				
51701	Huvepharma NV Belgium	Monensin sodium (Coxidin)	<p><i>Additive composition</i></p> <p>Monensin sodium technical substance equivalent to monensin activity: 25 %</p> <p>Perlite: 15 – 20 %</p> <p>Calcium Carbonate: qs. 100 %</p> <p><i>Active substance</i></p> <p>$C_{36}H_{61}O_{11}Na$</p> <p>Sodium salt of polyether monocarboxylic acid produced by <i>Streptomyces cinnamonensis</i> 28682, LMG S-19095 in powder form</p> <p>Factor composition</p> <p>Monensin A: not less than 90 %</p> <p>Monensin A + B: not less than 95 %</p> <p>Monensin C: 0,2 – 0,3 %</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Method 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)</p>	Chickens for fattening	—	100	125	<ol style="list-style-type: none"> Use prohibited at least 1 day before slaughter. The additive shall be incorporated in compound feedingstuffs in form of a granulated premixture. Monensin sodium shall not be mixed with other coccidiostats. Indicate in the instructions for use: <ul style="list-style-type: none"> “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”. Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation in the premise, wear suitable respiratory equipments. 	10.6.2021	<p>25 µg monensin sodium/kg of wet skin + fat</p> <p>8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle</p>
				Turkeys	16 weeks	60	100			

⁽¹⁾ Details 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