

Commission Regulation (EC) No 109/2007 of 5 February  
2007 concerning the authorisation of monensin sodium  
(Coxidin) as a feed additive (Text with EEA relevance)

COMMISSION REGULATION (EC) No 109/2007  
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concerning the authorisation of monensin sodium (Coxidin) as a feed additive  
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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<sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns authorisation of the substance monensin sodium (Coxidin) as a feed additive for chickens for fattening and turkeys, to be classified in the additive category 'occidiostats and histomonostats'.
- (4) The European Food Safety Authority (the Authority) concluded in its opinion of 20 October 2005 that monensin sodium (Coxidin) does not have an adverse effect on animal health, human health or the environment<sup>(2)</sup>. The Authority further concluded that monensin sodium (Coxidin) does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that product may be effectively used to prevent coccidiosis. This opinion also verified the report on the method of analysis of that feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003. The Authority concluded that it was necessary to establish maximum residue limits (MRLs). However, it was unable to propose MRLs since the applicant had not provided the data required. After receiving those data the Authority adopted an opinion proposing provisional MRLs on 21 November 2006<sup>(3)</sup>. It may be necessary to review the MRLs set out in the Annex to this Regulation in the light of the results of a future evaluation of the active substance concerned by the European Agency for the Evaluation of Medicinal Products.

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 109/2007. (See end of Document for details)

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- (5) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.
- (6) 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 substance, specified in the Annex, belonging to the additive category ‘coccidiostats and histomonostats’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

This Regulation shall enter into force on the 20th day following that of 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.

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## I<sup>F1</sup> ANNEX

### Textual Amendments

**F1** Substituted by 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).

Identification number of the additive	Name of the holder of authorisation	Additive (name)	Chemical formula or description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End 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 %	mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Coccidiostats and histomonostats										
51701	Huvepharm NV Belgium	Monensin sodium (Coxidin)		Chickens for fattening	16 weeks	100	125	1.	6.2.2017	725 µg monensin sodium/kg of wet skin + fat
				Turkeys	16 weeks	60	100	2.		8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle
								3.		Maximum permitted dose of monensin sodium
										Use prohibited at least 1 day before slaughter. The additive shall be incorporated in compound feedingstuffs in form a premixture.

**a** 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](http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)

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			acid produced by <i>Streptomyces cinnamomensis</i> 28682, LMG S-19095 in powder form						in complementary feedingstuffs: 625 mg/kg for chickens for fattening, 500 mg/kg for turkeys.
			Factor composition						
			Monensin A:					4.	Monensin sodium shall not be mixed with other coccidiostats.
			not less than 90 %						
			Monensin A + B:					5.	Indicate in the instructions for use:
			not less than 95 %						
			Monensin C:						
			0,2						Dangerous for equines.
			–						This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used
			0,3 %						
			<i>Analytical method<sup>a</sup></i>						
			Method for determination of the active substance: high performance liquid chromatography (HPLC) with post-column derivatisation and						

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				UV detection (λ = 520nm)			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.
51701	Huvepharm NV Belgium	Monensin sodium (Coxidin)	<del>Chickens</del> <del>composition</del> fattening	100	125	1.	10.6.2025 Use prohibited at least 1 day before slaughter
			Turkeys 16 weeks	60 technical substance equivalent to monensin activity: 25 % Perlite: 15 — 20 % Calcium Carbonate: qs. 100 %	100	2.	The additive shall be incorporated in compound feeding stuffs in form of a granulated premixture.
			<i>Active substance</i> C <sub>36</sub> H <sub>61</sub> O <sub>11</sub> Na				225 µg monensin sodium/ kg of wet skin + fat 8 µg monensin sodium/ kg of wet liver, wet kidney and wet muscle

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				<p>Sodium salt of polyether monocarboxylic acid produced by <i>Streptomyces cinnamomensis</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<sup>a</sup></i></p> <p>Method for determination of the active substance: high-performance liquid chromatography (HPLC) with</p>	<p>3. Monensin sodium shall not be mixed with other coccidiostats.</p> <p>4. 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>5. Wear suitable protective clothing, gloves and eye/face</p>
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**a** Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: [http://imm.jrc.ec.europa.eu/EURLs/EURL\\_feed\\_additives/Pages/index.aspx](http://imm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx)

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				post-column derivatisation and UV-VIS detection (EN ISO standard method 14183:2008)				protection. In case of insufficient ventilation in the premise, wear suitable respiratory equipments.
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- (1) [OJ L 268, 18.10.2003, p. 29](#). Regulation as amended by Commission Regulation (EC) No 378/2005 ([OJ L 59, 5.3.2005, p. 8](#)).
- (2) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on a request from the European Commission of the coccidiostat COXIDIN (monensin sodium), adopted on 20 October 2005, *The EFSA Journal* (2005) 283, p. 1-53.
- (3) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the Maximum Residues Limits for monensin sodium for chicken and turkeys for fattening, adopted on 21 November 2006, *The EFSA Journal* (2006) 413, p. 1-13. See also opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety of COXIDIN (monensin sodium), adopted on 12 July 2006, *The EFSA Journal* (2006) 381, p. 1-10.



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