

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2047**of 23 November 2021****concerning the authorisation of amprolium hydrochloride (COXAM) as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation: HuvePharma NV)****(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 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of amprolium hydrochloride (COXAM). That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns the authorisation of amprolium hydrochloride (COXAM) as a feed additive for chickens for fattening and chickens reared for laying, to be classified in the additive category 'coccidiostats and histomonostats'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 13 June 2018 ⁽²⁾ and 27 January 2021 ⁽³⁾ that, under the proposed conditions of use, the amprolium hydrochloride (COXAM) does not have an adverse effect on animal health and the environment. It also concluded that the additive should be considered a potential respiratory and skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that it cannot independently evaluate all data relevant to the current application due to the lack of provided data and is therefore unable to conclude on the safety of the additive for the consumer. The Authority further concluded that the additive is efficacious in controlling coccidiosis in chickens for fattening, and that this conclusion is extended to chickens reared for laying. The Authority also concluded that a post-market monitoring plan to monitor the *Eimeria* spp. resistance should be undertaken. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) Amprolium hydrochloride has already been evaluated by the European Medicines Agency Committee for Medicinal Products for Veterinary Use (EMA CVMP). In its report from January 2001 ⁽⁴⁾, EMA CVMP concluded that there is no need to establish a maximum residue limit (MRL) for amprolium. Therefore amprolium for poultry is listed in Table 1 of the Annex to Commission Regulation (EC) No 37/2010 ⁽⁵⁾. On these grounds, the safety of amprolium hydrochloride for the consumer has been sufficiently demonstrated according to Article 8(4)(e) of Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2018;16(7):5338.

⁽³⁾ EFSA Journal 2021;19(3):6457.

⁽⁴⁾ EMA CVMP (European Medicines Agency Committee for Medicinal Products for Veterinary Use), 2001. Amprolium Summary Report (2). EMEA/MRL/767/00-FINAL. January 2001. https://www.ema.europa.eu/en/documents/mrl-report/amprolium-summary-report-2-committee-veterinary-medicinal-products_en.pdf

⁽⁵⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

- (6) The assessment of amprolium hydrochloride (COXAM) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Entry into force

This Regulation shall enter into force on the twentieth 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.

Done at Brussels, 23 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of additive	Name of the holder authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			

Additive category: coccidiostats and histomonostats

51777	HuvePharma NV	Amprolium hydrochloride (COXAM)	<p>Additive composition Amprolium HCl: 250 g/kg Liquid paraffin: 30 g/kg Rice hulls q.s. to 1,000 g.</p> <p>Characterisation of the active substance Amprolium hydrochloride (> 97,5 % purity) C₁₄H₁₉ClN₄.HCl, (1-[4-amino-2-propyl-5-pyrimidinyl)methyl]-2-methylpyridinium chloride monohydrochloride, CAS Number: 137-88-2 Related impurities: 2-picoline < 0,52 % sulfated ash ≤ 0,1 %</p> <p>Analytical method ⁽¹⁾ For the quantification of amprolium in the feed additive: — Reversed-Phase High Performance Liquid Chromatography using Ultraviolet detection at 268 nm (RP-HPLC-UV). For the quantification of amprolium in premixtures and feedingstuffs:</p>	Chickens for fattening Chickens reared for laying	-	125	125	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. The additive shall not be mixed with other coccidiostats. 4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: resistance to bacteria and <i>Eimeria</i> spp. 	14.12.2031
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			<p>— Cation exchange High Performance Liquid Chromatography using Ultraviolet detection at 264 nm (IE-HPLC-UV) – Regulation (EC) No 152/2009.</p>					<p>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection.</p>	
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(¹) <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>