

COMMISSION REGULATION (EC) No 244/2007**of 7 March 2007****concerning the authorisation of L-histidine monohydrochloride monohydrate 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 ⁽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 authorisation.
- (2) An application for authorisation has been submitted for L-histidine monohydrochloride monohydrate as an amino acid.
- (3) As the application for authorisation was submitted before the date of application of Regulation (EC) No 1831/2003, it was submitted under Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁽²⁾. As from 18 October 2004, amino acids, their salts and analogues fall under the scope of Regulation (EC) No 1831/2003. The application is therefore to be considered as an application under Article 7 of Regulation (EC) No 1831/2003.
- (4) In order to comply with the requirements laid down in Article 7 of Regulation (EC) No 1831/2003, additional information was submitted in support of the application.
- (5) The application concerns authorisation of L-histidine monohydrochloride monohydrate as a feed additive for salmonids, to be classified in the additive category 'nutritional additives' and the functional group 'amino acids, their salts and analogues'.

- (6) The European Food Safety Authority (the Authority) concluded in its opinions of 2 March 2005 ⁽³⁾ and of 18 October 2006 ⁽⁴⁾ that L-histidine monohydrochloride monohydrate does not have an adverse effect on animal health, human health or the environment. It further concluded that L-histidine monohydrochloride monohydrate 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, it is an essential amino acid also for fish, and the use of that preparation has been shown to prevent cataracts under farming conditions for salmonids. The opinion of the Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. The report on the method of analysis of the feed additive in feed was submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003 to the Authority. 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.
- (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 preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', 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 its publication in the *Official Journal of the European Union*.

⁽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⁾ OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

⁽³⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and the bioavailability of product L-Histidine monohydrochloride monohydrate for salmonids. Adopted on 2 March 2005. *The EFSA Journal* (2005) 195, p. 1.

⁽⁴⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed under Regulation (EC) 1831/2003 on L-Histidine monohydrochloride monohydrate as feed additive for use in salmonids. Adopted on 18 October 2006. *The EFSA Journal* (2006) 407, p. 1.

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

Done at Brussels, 7 March 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

Identification number of the additive	Name of the holder of 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
						Maximum content in mg/kg of complete feedingstuff			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c3.5.1	—	L-histidine mono-hydrochloride monohydrate	Characterisation of the additive L-histidine monohydrochloride monohydrate 98 % produced by <i>Escherichia coli</i> (ATCC 9637) C ₃ H ₃ N ₂ -CH ₂ -CH(NH ₂)-COOH· HCl· H ₂ O Analytical method Community method for the determination of aminoacids (Commission Directive 98/64/EC amending Directive 71/393/EEC ⁽¹⁾)	Salmonids	—	—	—	—	2.4.2017

⁽¹⁾ OJ L 257, 19.9.1998, p. 14