

COMMISSION REGULATION (EC) No 393/2008
of 30 April 2008
concerning the authorisation of astaxanthin dimethylsuccinate 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) 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 Regulation (EC) No 1831/2003.
- (3) The application concerns authorisation of the preparation of astaxanthin dimethylsuccinate as a feed additive for salmon and trout, to be classified in the additive category 'sensory additives'.
- (4) The European Food Safety Authority (the Authority) concluded in its opinion of 17 October 2007 that astaxanthin dimethylsuccinate does not have an adverse effect on animal health, human health or the environment⁽²⁾. It further concluded that astaxanthin dimethylsuccinate does not present any other risk which would,

in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. It does not consider that there is a need for specific requirements of post market monitoring. This opinion also verifies the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (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 preparation specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'a(ii) Colourants; substances which when fed to animals add colours to food of animal origin', 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.

Done at Brussels, 30 April 2008.

For the Commission
Androulla VASSILOU
Member of the Commission

⁽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 entitled 'on the safety and efficacy of Carophyll® Stay-Pink (astaxanthin dimethylsuccinate) as a feed additive for salmon and trout'. Adopted on 17 October 2007. *The EFSA Journal* (2007) 574, p. 1-25.

ANNEX

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
						mg/kg of complete feedingsstuff with a moisture content of 12 %	mg/kg of complete feedingsstuff with a moisture content of 12 %			
Category: sensory additives. Functional group: a(ii) Colourants; substances which when fed to animals add colours to food of animal origin										
2a(ii) 165	—	Astaxanthin dimethylsuccinate	<p>Active substance: Astaxanthin dimethylsuccinate (C₅₀H₆₄O₁₀; CAS No: 578006-46-9) Astaxanthin dimethylsuccinate > 96 % Other carotenoids < 4 % Additive composition: Formulated in an organic matrix</p> <p>Purity criteria: Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg of additive Dichloromethane: ≤ 600 mg/kg additive</p> <p>Analytical methods: High performance liquid chromatography (HPLC) coupled with ultraviolet detection (UV) ⁽¹⁾</p>	Salmon and trout	—	—	138	<p>1. Use permitted from the age of 6 months onwards or from 50 g weight onwards.</p> <p>2. In order to be used in fish feed, the additive shall be used in a formulated form, properly stabilized with authorized antioxidants. If ethoxyquin is used in the formulation, the ethoxyquin content shall be indicated in the label.</p> <p>3. If astaxanthin dimethylsuccinate is mixed with canthaxanthin and other astaxanthin sources, the total concentration of the mixture shall not exceed 100 g astaxanthin-equivalents ⁽²⁾/kg in the complete fish feedingsstuff.</p>	21 May 2018	

⁽¹⁾ Further details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

⁽²⁾ 1,38 mg astaxanthin dimethylsuccinate is equivalent to 1 mg astaxanthin.