

COMMISSION IMPLEMENTING REGULATION (EU) 2016/896
of 8 June 2016
concerning the authorisation of iron sodium tartrates as a feed additive for all animal species
(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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of iron sodium tartrates. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of iron sodium tartrates as a feed additive for all animal species, to be classified in the additive category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 April 2015 ⁽²⁾ that, under the proposed conditions of use, the preparation concerned does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparation has the potential to be efficacious as an anti-caking agent in salt. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of iron sodium tartrates 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 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 Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'anti-caking agents' 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2015; 13(5):4114.

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

Done at Brussels, 8 June 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of NaCl			

Technological additives: anti-caking agents

1i534	Iron sodium tartrates	<p><i>Additive composition</i></p> <p>Preparation of complexation products of sodium tartrates with iron(III) chloride in water solution ≤ 35 % (by weight).</p> <p><i>Characterisation of active substance</i></p> <p>Iron(III) complexation product of D(+)-, L(-) and meso-2,3-dihydroxybutanedioic acids</p> <p>Ratio: iron to meso-tartrate 1:1;</p> <p>Ratio: iron to total tartrate isomers 1:1,5</p> <p>CAS number 1280193-05-9</p> <p>$\text{Fe(OH)}_2\text{C}_4\text{H}_4\text{O}_6\text{Na}$</p> <p>Chloride: ≤ 25 %</p> <p>Oxalates: ≤ 1,5 % expressed as oxalic acid</p> <p>Iron: ≥ 8 % iron(III)</p> <p><i>Analytical method ⁽¹⁾</i></p> <p>Quantification of meso-tartrate and D(-), L(+)-tartrates in the feed additive:</p> <p>— High Performance Liquid Chromatography with Refraction Index detection (HPLC-RI);</p> <p>Quantification of total iron in the feed additive:</p> <p>— Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) — EN 15510, or</p>	All animals species	—	—	—	<ol style="list-style-type: none"> The additive shall be used only in NaCl (sodium chloride). Minimum recommended dose: 26 mg of iron sodium tartrates/kg NaCl (equivalent to 3 mg iron/kg of NaCl). Maximum recommended dose: 106 mg of iron sodium tartrates/kg NaCl. 	29 June 2026
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					mg of active substance/kg of NaCl			
		<ul style="list-style-type: none"> — Inductively Coupled Plasma Atomic Emission Spectroscopy after pressure digestion (ICP-AES) — EN 15621, or — Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) — EN ISO 11885, or — Atomic Absorption Spectrometry (AAS) — EN ISO 6869, or — Atomic Absorption Spectrometry (AAS) — Commission Regulation (EC) No 152/2009 ^(?); and <p>Quantification of total sodium in the feed additive:</p> <ul style="list-style-type: none"> — Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) — EN 15510; or — Inductively Coupled Plasma Atomic Emission Spectroscopy after pressure digestion (ICP-AES) — EN 15621; or — Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP-AES) — EN ISO 11885; or — Atomic Absorption Spectrometry (AAS) — EN ISO 6869; and <p>Quantification of total chloride in the feed additive:</p> <ul style="list-style-type: none"> — Titrimetry — Regulation (EC) No 152/2009 or ISO 6495. 						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽²⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).