

COMMISSION DECISION

of 14 June 2010

authorising the placing on the market of Ferric Sodium EDTA as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

*(notified under document C(2010) 3729)***(Only the German text is authentic)**

(2010/331/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁽¹⁾, and in particular Article 7 thereof,

Whereas:

Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements⁽³⁾ and/or Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods⁽⁴⁾ lay down specific provision for the use of vitamins, minerals and other substances in food. The use of Ferric Sodium EDTA should be authorised without prejudice to the requirements of this legislation. The limits set in Annex II of this Decision relate exclusively to EDTA as such and are without prejudice to any limits for the addition of iron to foods. On the basis of the scientific assessment it is established that Ferric Sodium EDTA complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(1) On 4 September 2006 the company Akzo Nobel Chemicals GmbH made a request to the competent authorities of the United Kingdom to place Ferric Sodium EDTA on the market as a novel food ingredient.

(2) On 11 September 2006 the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that an additional assessment was required.

(3) The Commission informed all Member States about the request on 27 November 2006. EFSA was requested to carry out the assessment on 22 December 2006.

(4) On 26 November 2009 following a request from the Commission, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted an opinion on the safety of Ferric Sodium EDTA. In the opinion EFSA concluded that EDTA is of no safety concern as long as the intake of EDTA does not exceed 1,9 mg EDTA per kg bodyweight per day.

(5) Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses⁽²⁾, Directive 2002/46/EC of the European

(6) In order to ensure that children will not exceed the Acceptable Daily Intake (ADI) of EDTA it appears appropriate to set limits for the addition of EDTA to foods.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Ferric Sodium EDTA as a source of iron as specified in the Annex I may be placed on the market in the Union as a novel food ingredient to be used in food without prejudice to the specific provisions of Regulation (EC) No 953/2009, Directive 2002/46/EC and/or Regulation (EC) No 1925/2006.

The maximum amount of Ferric Sodium EDTA (expressed as anhydrous EDTA) to be used in foods is set out in Annex II.

Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'Ferric Sodium EDTA'.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ OJ L 269, 14.10.2009, p. 9.

⁽³⁾ OJ L 183, 12.7.2002, p. 51.

⁽⁴⁾ OJ L 404, 30.12.2006, p. 26.

Article 3

This Decision is addressed to Akzo Nobel Chemicals GmbH, Kreuzauer Strasse 46, D — 52355 Düren.

Done at Brussels, 14 June 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX I

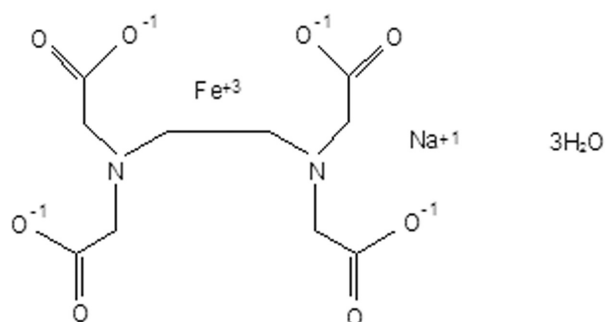
Specifications of Ferric Sodium EDTA**DESCRIPTION**

Ferric Sodium EDTA (ethylenediaminetetraacetic acid) is an odourless free-flowing, yellow to brown powder with a chemical purity of more than 99 % (w/w). It is freely soluble in water.

CAS No: 18154-32-0 (CAS anhydrous 15708-41-5)

Chemical Formula: $\text{C}_{10}\text{H}_{12}\text{FeN}_2\text{NaO}_8 \cdot 3\text{H}_2\text{O}$

Structural Formula:



Chemical characteristics of Ferric Sodium EDTA without prejudice to the provisions of Regulation (EC) No 953/2009, Directive 2002/46/EC and/or Regulation (EC) No 1925/2006

pH of 1 % solution	3,5 to 5,5
Iron	12,5 % to 13,5 %
Sodium	5,5 %
Water	12,8 %
Organic matter (CHNO)	68,4 %
EDTA	65,5 % to 70,5 %
Water insoluble matter	not more than 0,1 %
Nitrilo-triacetic acid	not more than 0,1 %

ANNEX II

Maximum amounts of Ferric Sodium EDTA (expressed as anhydrous EDTA)

Food supplements (in accordance with Directive 2002/46/EC)	children: 18 mg per daily dose as recommended by the manufacturer
	adults: 75 mg per daily dose as recommended by the manufacturer
Dietetic foods (in accordance with Regulation (EC) No 953/2009)	12 mg EDTA per 100 g of final food
Fortified foods (in accordance with Regulation (EC) No 1925/2006)	12 mg EDTA per 100 g of final food