

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 26 May 2008

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

(notified under document number C(2008) 1954)

(Only the German text is authentic)

(2008/413/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

marketing of the product were raised in accordance with that provision.

Having regard to the Treaty establishing the European Community,

(5) Therefore the European Food Safety Authority (EFSA) was consulted on 28 October 2006.

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,

(6) On 6 July 2007 EFSA adopted the 'Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of alpha-cyclodextrin'.

Whereas:

(1) On 12 October 2004 the company Wacker Chemie made a request to the competent authorities of Belgium to place alpha-cyclodextrin on the market as a novel food ingredient.

(7) In the opinion the panel came to the conclusion that there are no safety concerns at the proposed use levels and anticipated consumption of alpha-cyclodextrin.

(2) On 29 June 2005 the competent food assessment body of Belgium issued its initial assessment report. In that report it came to the conclusion that alpha-cyclodextrin is safe for human consumption.

(8) On the basis of the scientific assessment, it is established that alpha-cyclodextrin complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(3) The Commission forwarded the initial assessment report to all Member States on 28 September 2005.

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

(4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the

HAS ADOPTED THIS DECISION:

Article 1

⁽¹⁾ OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

Alpha-cyclodextrin as specified in the Annex may be placed on the market in the Community as a novel food ingredient.

Article 2

The designation 'alpha-cyclodextrin' or 'α-cyclodextrin' shall be displayed in the list of ingredients of the foods containing it.

Article 3

This Decision is addressed to Wacker, Consortium für elektrochemische Chemie GmbH, Zielstattstrasse 20, D-81379 München.

Done at Brussels, 26 May 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

SPECIFICATIONS OF ALPHA-CYCLODEXTRIN

Synonyms

α -cyclodextrin, α -dextrin, cyclohexaamylose, cyclomaltohexaose, α -cycloamylase

Definition

A non-reducing cyclic saccharide consisting of six α -1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolyzed starch. Recovery and purification of α -cyclodextrin may be carried out using one of the following procedures: precipitation of a complex of α -cyclodextrin with 1-decanol, dissolution in water at elevated temperature and re-precipitation, steam-stripping of the complexant, and crystallisation of α -cyclodextrin from the solution; or chromatography with ion-exchange or gel filtration followed by crystallisation of α -cyclodextrin from the purified mother liquor; or membrane separation methods such as ultra-filtration and reverse osmosis.

Chemical name

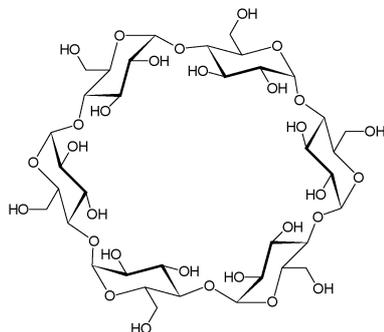
Cyclohexaamylose

CAS. number

10016-20-3

Chemical formula

$(C_6H_{10}O_5)_6$

Structural formula**Formula weight**

972,85

Assay

Not less than 98 % (dry basis)

Description

Virtually odorless, white or almost white crystalline solid.

Characteristics**Identification**

Melting range	Decomposes above 278 °C
Solubility	Freely soluble in water; very slightly soluble in ethanol
Specific rotation	$[\alpha]_{25}^D$: Between +145° and +151° (1 % solution)
Chromatography	The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for α -cyclodextrin in a chromatogram of reference α -cyclodextrin (available from Consortium für Elektrochemische Industrie GmbH, München, Germany or Wacker Biochem Group, Adrian, MI, USA) using the conditions described in the METHOD OF ASSAY

Purity

Water	Not more than 11 % (Karl Fischer Method)
Residual complexant (1-decanol)	Not more than 20 mg/kg
Reducing substances	Not more than 0,5 % (as glucose)
Sulfated ash	Not more than 0,1 %
Lead	Not more than 0,5 mg/kg

Method of assay

Determine by liquid chromatography using the following conditions:

Sample solution: Weigh accurately about 100 mg of test sample into a 10-ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath (10-15 min) and dilute to the mark with purified deionised water. Filter through a 0,45-micrometer filter.

Reference solution: Weigh accurately about 100 mg of α -cyclodextrin into a 10-ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath and dilute to the mark with purified deionised water.

Chromatography: Liquid chromatograph equipped with a refractive index detector and an integrating recorder.

Column and packing: Nucleosil-100-NH2 (10 μ m) (Macherey & Nagel Co. Düren, Germany) or similar.

Length: 250 mm

Diameter: 4 mm

Temperature: 40 °C

Mobile phase: acetonitrile/water (67/33, v/v)

Flow rate: 2,0 ml/min

Injection volume: 10 μ l

Procedure: Inject the sample solution into the chromatograph, record the chromatogram, and measure the area of the α -CD peak. Calculate the percentage of α -cyclodextrin in the test sample as follows:

$$\% \alpha\text{-cyclodextrin (dry basis)} = 100 \times (A_S/A_R) (W_R/W_S)$$

where

A_S and A_R are the areas of the peaks due to α -cyclodextrin for the sample solution and reference solution, respectively.

W_S and W_R are the weights (mg) of the test sample and reference α -cyclodextrin, respectively, after correcting for water content.
