

COMMISSION DECISION**of 25 September 2001****authorising the placing on the market of trehalose as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document number C(2001) 2687)*

(2001/721/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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,

Having regard to the request by Bioresco Ltd, Switzerland on behalf of Hayashibara Co. Ltd, Japan to the competent authorities of United Kingdom of 25 May 2000 for placing trehalose on the market as a novel food or novel food ingredient,

Having regard to the initial assessment report drawn up by the competent authorities of the United Kingdom.

Whereas:

- (1) While trehalose extracted from yeast was approved for use in foods (except for infant formulae and follow-on formulae) in 1991 in the United Kingdom, it still has to be considered as novel because significant amounts of trehalose have not been marketed subsequently in the United Kingdom or other Member States.
- (2) In their initial assessment report the United Kingdom's competent food assessment body came to the conclusion that the trehalose as specified by JECFA at its 55th meeting is safe for human consumption within the range of foodstuffs detailed by the company.
- (3) The Commission forwarded the initial assessment report to all Member States on 16 October 2000.
- (4) Within the 60 day-period laid down in Article 6(4) of the Regulation, reasoned objections to the marketing of the product were nevertheless raised in accordance with that provision.
- (5) At a meeting on 12 March 2001 Bioresco provided additional information responding to the comments and objections raised by Member States.

- (6) On the basis of this additional information and the initial assessment report, it is established that trehalose complies with the criteria laid down in Article 3(1) of the Regulation.
- (7) The use of trehalose in foods for particular uses is governed by specific requirements in Community law.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DECISION:

Article 1

Trehalose as specified in the Annex, may be placed on the market in the Community as novel food or novel food ingredient for use in foodstuffs.

Article 2

The designation 'trehalose' shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.

In a prominently displayed footnote related to the designation trehalose by means of an asterisk (*) the words 'trehalose is a source of glucose' shall be displayed. The words shall have a typeface of at least the same size as the list of ingredients itself.

Article 3

This Decision is addressed to Bioresco Ltd Bundesstraße 29, CH-4054 Basel.

Done at Brussels, 25 September 2001.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

ANNEX

SPECIFICATIONS OF TREHALOSE

Synonyms

α,α -trehalose

Definition

A non-reducing disaccharide that consists of two glucose moieties linked by an α -1,1-glucosidic bond. It is obtained from liquefied starch by a multistep enzymatic process. The commercial product is the dihydrate.

Chemical name

α -D-glucopyranosyl- α -D-glucopyranoside, dihydrate

CAS No

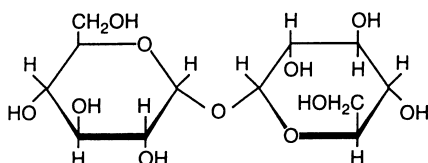
6138-23-4 (dihydrate)

Chemical formula

$C_{12}H_{22}O_{11} \cdot 2H_2O$ (dihydrate)

Structural formula

Trehalose



Formula weight

378,33 (dihydrate)

Assay

Not less than 98 % on the dry basis.

Description

Virtually odourless, white or almost white crystals with a sweet taste

Characteristics

Identification

Solubility

Freely soluble in water, very slightly soluble in ethanol

Specific rotation

$[\alpha]_D^{20} + 199^\circ$ (5 % aqueous solution)

Melting point

97 °C (dihydrate)

Purity

Loss on drying

Not more than 1,5 % (60 °, 5h)

Total ash

Not more than 0,05 %

Lead

Not more than 1 mg/kg

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5 ⁽¹⁾, 'Instrumental methods'

Method of assay

Principle: trehalose is identified by liquid chromatography and quantified by comparison to a reference standard containing standard trehalose

Preparation of sample solution: weigh accurately about 3 g of dry sample into a 100-ml volumetric flask and add about 80 ml of purified, deionised water. Bring sample to complete dissolution and dilute to mark with purified deionised water. Filter through a 0,45 micron filter

Preparation of standard solution: dissolve accurately weighed quantities of dry standard reference trehalose in water to obtain a solution having known concentration of about 30 mg of trehalose per ml

Apparatus: liquid chromatograph equipped with a refractive index detector and integrating recorder

Conditions:

Column: Shodex Ionpack KS-801 (Showa Denko Co.) or equivalent

— length: 300 mm

— diameter: 10 mm

— temperature: 50 °C

Mobile phase: water

flow rate: 0,4 ml/min

Injection volume: 8 µl

Procedure: inject separately equal volumes of the sample solution and the standard solution into the chromatograph. Record the chromatograms and measure the size of response of the trehalose peak

Calculate the quantity, in mg, of trehalose in 1 ml of the sample solution by the following formula:

$$\% \text{ trehalose} = 100 \times (R_U/R_S) (W_S/W_U)$$

where

R_S = peak area of trehalose in the standard preparation

R_U = peak area of trehalose in the sample preparation

W_S = weight in mg of trehalose in the standard preparation

W_U = weight of dry sample in mg

⁽¹⁾ Food and nutrition paper 5 Rev.2 — Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 322p. English — ISBN 02991.