DECISIONS

COMMISSION IMPLEMENTING DECISION

of 19 August 2011

authorising the placing on the market of Phosphatidylserine from soya phospholipids as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2011) 5897)

(2011/513/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:

(1) On 28 September 2009 the company Cantox Health Science International on behalf of the company Enzymotec Ltd made a request to the competent authorities of Finland to place Phosphatidylserine from soya phospholipids on the market as novel food ingredient.

(2) On 14 April 2010 the competent food assessment body of Finland issued its initial assessment report. In that report it came to the conclusion that the company Enzymotec has provided sufficient information to authorise the placing on the market of Phosphatidylserine from soya phospholipids as a novel food ingredient.

(3) The Commission forwarded the initial assessment report to all Member States on 21 April 2010.

(4) Within the 60 days-period laid down in Article 6(4) of Regulation (EC) No 258/97, one reasoned objection to the marketing of the product, which concerns the maximum daily intake, was raised in accordance with that provision. In accordance with the provisions of Article 6(4) a Commission implementing Decision is required that takes into account the reasoned objection raised.

(5) Phosphatidylserine from soya phospholipids complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(6) 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

Phosphatidylserine from soya phospholipids as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses specified in Annex II.

Article 2

The designation of Phosphatidylserine from soya phospholipids authorised by this Decision on the labelling of the foodstuff containing it shall be 'Soya phosphatidylserine'.

Article 3

This Decision is addressed to Enzymotec Ltd, P.O. Box 6, Migdal HaEmeq, 23106 Israel.

Done at Brussels, 19 August 2011.

For the Commission

John DALLI

Member of the Commission

[1] OJ L 43, 14.2.1997, p. 1.

ANNEX I

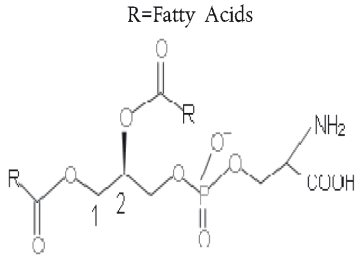
Specifications of Phosphatidylserine from soya phospholipids

Description:

The novel food ingredient is an off-white to light yellow powder. It is also available in liquid form with a clear brown to orange colour. The liquid form contains medium chain triacylglycerides (MCT) as a carrier. It contains lower levels of Phosphatidylserine due to the fact that it includes significant amounts of oil (MCT).

Phosphatidylserine from soya phospholipids is obtained through enzymatic transphosphatidylation of high-phosphatidylcholine soybean lecithin with the amino acid L-serine. Phosphatidylserine consists of a glycerophosphate skeleton conjugated with two fatty acids and L-serine via a phosphodiester linkage.

Structural Formula:



Characteristics of Phosphatidylserine from soya phospholipids		
Parameter	Powder Form	Liquid Form
Moisture	less than 2 %	less than 2 %
Phospholipids	not less than 85 %	not less than 25 %
Phosphatidylserine	not less than 61 %	not less than 20 %
Glycerides	less than 2 %	not applicable
free L-serine	less than 1 %	less than 1 %
Tocopherols	less than 0,3 %	less than 0,3 %
Phytosterols	less than 0,2 %	less than 0,2 %

ANNEX II

Use-Level (mg) of Phosphatidylserine from soya phospholipids	
Beverages based on yoghurt	50 mg/100 ml
Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready to drink)
Foods based on yoghurt	80 mg/100 g
Cereal bars	350 mg/100 g
Chocolate based confectionary	200 mg/100 g

Phosphatidylserine from soya phospholipids may be used in food for special medical purposes only in compliance with Commission Directive 1999/21/EC [1].

[1] OJ L 91, 7.4.1999, p. 29.