

LETTER  
Placing a novel food on  
the market

Courtesy translation

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Ref: Regulation (EC) No 258/97 Article 4 (2), first indent

**SUBJECT: PHOSPHOLIPID PRODUCT MEMREEPLUS-40P CONTAINING PHOSPHATIDYL-SERINE AND PHOSPHATIDIC ACID**

This letter is to inform you of the results of the review procedure carried out pursuant to Articles 4 and 6 of Regulation (EC) No 258/97 on the novel food application "MemreePlus<sup>TM</sup>-40P phosphatidylserine and phosphatidic acid standardised phospholipid powder product" submitted to the Finnish Food Safety Authority Evira.

Lipogen Products (9000) Ltd submitted on 25 January 2016 to Evira an application concerning a novel food as referred to in Regulation (EC) No 258/97. The application concerned the use of phospholipid product Memreeplus<sup>TM</sup>-40P containing phosphatidylserine and phosphatidic acid as a novel food ingredient.

Evira submitted the application on 19 February 2016 to the Finnish Novel Food Board that carries out food assessments for performance of the initial assessment referred to in Article 6. The Novel Food Board submitted to Evira on 22 April 2016 the initial assessment report, which stated that MemreePlus<sup>TM</sup>-40P as a novel food ingredient fulfils the conditions laid down in Article 3(1) in the Novel Food Regulation (EC) No 258/97 in the uses and at levels proposed by the application. The Board further stated that as the product may be expected to involve problems for consumers suffering from soy allergies, the labelling of foods containing MemreePlus<sup>TM</sup>-40P derived from soy lecithin should show the information to the consumers that the source of the product is soy.

The Commission forwarded the initial assessment report to all Member States on 3 August 2016. No reasoned objections were presented within the period of 60 days confirmed in Regulation (EC) No 258/97, Article 6(4) on the use of phospholipid product Memreeplus<sup>TM</sup>-40P containing phosphatidylserine and phosphatidic acid as a novel food ingredient as presented in the application. Germany, the United Kingdom and the Netherlands raised questions which were replied by the applicant and the Novel Food Board in a manner that satisfied the Member States concerned.

Based on the aforesaid, phospholipid product Memreeplus™-40P containing phosphatidylserine and phosphatidic acid meets the requirements laid down in Regulation (EC) No 258/97, Article 3(1) and the placing on the market of the product concerned can be authorised on the following conditions:

## 1) Product specification:

<b>Parameter</b>	<b>MemreePlus™-40P (powder)</b>
Moisture	not more than 2%
Total phospholipids	not less than 70%
Phosphatidylserine	not less than 20%
Phosphatidic acid	not less than 20%
Glycerides	not more than 1%
Free L-serine	not more than 1%
Tocopherols	not more than 0.3%
Phytosterols	not more than 2%

Silicon dioxide is used in the product as anti-caking agent with a maximum content of 1%.

## 2) Uses of the product:

<b>Food product</b>	<b>Phosphatidylserine + phosphatidic acid (mg/100 g)</b>	<b>Phosphatidylserine + phosphatidic acid total (mg/serving)</b>	<b>Serving size</b>
Breakfast cereals	80 + 80	30	35 g
Cereal bars	350 + 350	100	30 g
Foods based on yogurt	80 + 80	100	125 ml
Soy-based yogurt-like products	80 + 80	100	125 ml
Yogurt-based drinks	50 + 50	100	200 ml
Soy-based yogurt-like drinks	50 + 50	100	200 ml
Powders based on milk powder (ready-to-drink)	3.5 + 3.5 (40 + 40 / 100 ml)	100	8.75 g (250 ml)
Food supplements	-	800	daily dose recommended by manufacturer

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As concerns foods for special medical purposes and total diet replacements, the MemreePlus™-40P product is to be used in accordance with the conditions laid down in the special legislation concerning these products (Regulation (EU) No 609/2013 of the European Parliament and of the Council).

3) The product is not intended to be marketed to pregnant or breast-feeding women.

4) The labelling of foods containing the product shall indicate that the source of the product is soy, for example "soy phosphatidylserine and phosphatidic acid".

Lipogen Products (9000) Ltd. is authorised to place on the market phospholipid product Memreeplus™-40P containing phosphatidylserine and phosphatidic acid for use as a novel food ingredient according to the above presentations.

A copy of this letter is submitted to the Commission for valid publication and forwarding to all Member States.

Senior Inspector, Head of Section

Annika Nurttila

Senior Inspector

Sanna Viljakainen

ENCLOSURE

Initial assessment by Finnish Novel Food Board

FOR INFORMATION

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