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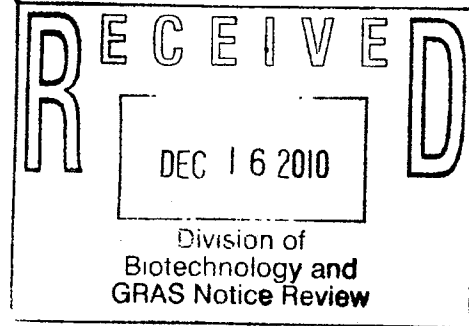
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# Soni & Associates Inc.

749 46<sup>th</sup> Square  
Vero Beach, FL 32968, USA  
Telephone: 772-299-0746  
Facsimile: 772-299-5381  
E-mail: sonim@bellsouth.net

December 14, 2010

Office of Food Additive Safety (HFS-255)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



**Subject: Notification of GRAS Determination for Krill Oil**

Dear Sir/Madam:

In accordance with proposed 21 CFR 170.36 (Notice of a claim for exemption based on a GRAS determination) published in Federal Register (62 FR 18938-18964; April 17, 1997), I am submitting in triplicate, as the agent of the notifier, Aker Biomarine Antarctic AS, Norway, a Generally Recognized As Safe (GRAS) notification for Superba® Krill Oil.

Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba* is intended for use as a food ingredient in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods, at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba® Krill Oil is estimated to result in a maximum daily intake of 8.28 g/person.

If you have any questions or require additional information, please feel free to contact me by phone at 772-299-0746 or by email at sonim@bellsouth.net.

Sincerely,

(b) (6)

Madhu G. Soni, Ph.D.

Enclosures:

[www.soniassociates.net](http://www.soniassociates.net)

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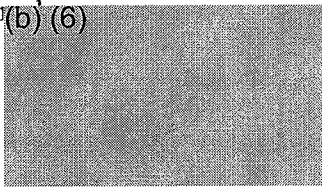
## GRAS NOTIFICATION

### I. Claim of GRAS Status

#### A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

Aker Biomarine Antarctic AS, Norway, has determined that high phospholipid krill oil is Generally Recognized As Safe, and therefore, exempt from the requirement of premarket approval, under the conditions of its intended use. This determination is based on scientific procedures as described in the following sections, under the conditions of krill oil's intended use in food, among experts qualified by scientific training and expertise.

Sig(b) (6)



Date 12/14/10

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Madhu G. Soni, Ph.D., FACN

Agent for:

Aker Biomarine Antarctic AS  
Fjordallèen 16, 0115 Oslo  
Norway

[www.soniassociates.net](http://www.soniassociates.net)

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**B. Name and Address of Notifier:**

Hogne Vik, M.D., Ph.D.  
EVP Documentation  
Aker Biomarine Antarctic AS  
Fjordallèen 16, 0115 Oslo  
Norway  
  
Tel: +47 24 13 00 00  
Fax: +47 24 13 01 10  
Email: hogne.vik@akerbiomarine.com

**C. Common or usual name of the notified substance:**

The common name of the substance of this notification is high phospholipid krill oil. The specific substance of this GRAS determination is Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba*. Superba™ Krill Oil is rich in omega-3 fatty acids, most of which are attached to phospholipids. Superba™ Krill Oil also contains astaxanthin ester.

**D. Conditions of use:**

High phospholipid krill oil is intended for use as a substitute or alternative to fish oils in the following food categories: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods<sup>1</sup>, at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba™ Krill Oil, in the above mentioned food categories, is estimated to result in a maximum daily intake of 8.28 g/person. The proposed use of Superba™ Krill Oil will provide a maximum daily consumption of up to 2.20 g/person/day of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

**E. Basis for GRAS Determination:**

In accordance with 21 CFR 170.30, high phospholipid krill oil has been determined to be Generally Recognized As Safe (GRAS) based on scientific procedures. A comprehensive search of the scientific literature was also utilized for this determination. There exists sufficient qualitative and quantitative scientific evidence, including human and animal data to determine safety-in-use for Superba™ Krill Oil. Recently, high phospholipid krill oil (GRN 000242) has been the subject of a GRAS notification, while two of its important component fatty acids, EPA and DHA as part of fish or algal oil, have been the subject of multiple GRAS notifications. In response to these notices, FDA did not question the conclusions that the use of high phospholipid krill oil or sources of fatty acids (EPA and DHA) is GRAS under the conditions described in the notices. The safety

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<sup>1</sup> Under Section 5(b) of the Orphan Drug Act (ODA), a Medical Food is defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. The intended use of krill oil in medical foods will be as per these and other applicable regulations.

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determination of high phospholipid krill oil is based on the totality of available scientific evidence that includes human observations and a variety of preclinical and clinical studies. Based on the available safety-related information, the estimated daily intake, if ingested daily over a lifetime, is safe.

**F. Availability of Information:**

The data and information that forms the basis for this GRAS determination will be provided to the Food and Drug Administration upon request and are located at the offices of:

Madhu G. Soni, Ph.D., FACN,  
Soni & Associates Inc.,  
749 46<sup>th</sup> Square,  
Vero Beach FL, 32968  
Phone: (772) 299-0746; E-mail: sonim@bellsouth.net

**II. Detailed Information About the Identity of the Notified Substance:**

**A. Trade Name:**

The subject of this notification will be marketed as Superba™ Krill Oil

**B. Physical Characteristics**

Superba™ Krill Oil is dark red colored viscous oil

**C. Chemical Abstract Registry Number:**

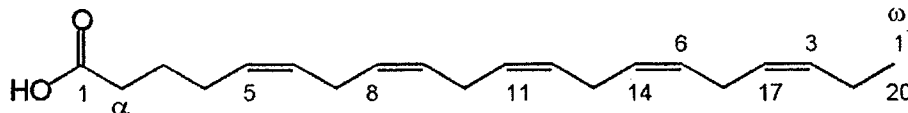
Not available

**D. Chemical Formula:**

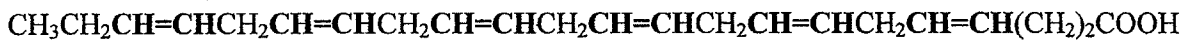
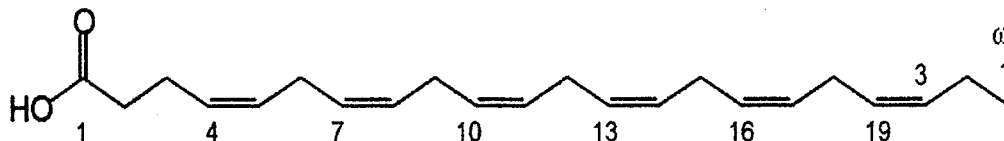
Not applicable

**E. Structure:**

The important constituents of high phospholipid krill oil are the fatty acids, EPA and DHA. The structures of these two fatty acids presented in Figure 1.



Eicosapentaenoic acid (EPA)



Docosahexaenoic acid (DHA)

Figure 1. Chemical structures of EPA and DHA

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