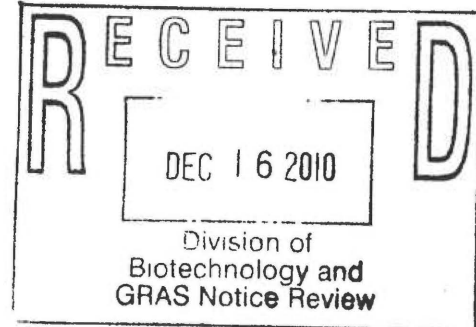


Soni & Associates Inc.

749 46th 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.

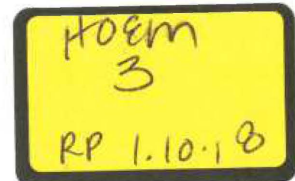
Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba* is intended for use as a food ingredient in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods, at use levels ranging from 0.05 to 0.50 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

000002

Soni & Associates Inc.

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

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

Madhu G. Soni, Ph.D., FACN

Agent for:

Aker Biomarine Antarctic AS
Fjordalléen 16, 0115 Oslo
Norway

0 0 0 0 0 0

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 foods¹, 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

¹ 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.

000004

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 46th 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:

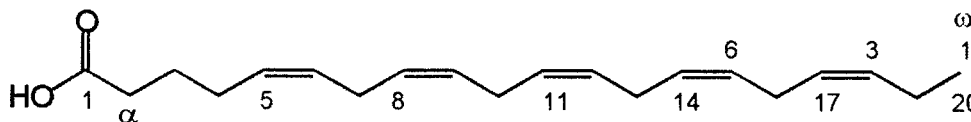
Not available

D. Chemical Formula:

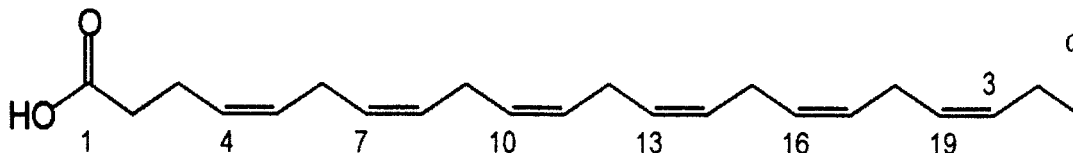
Not applicable

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

000005

F. Typical Composition and Specifications

Typical compositional analysis and specifications of Superba™ Krill Oil are presented in Table 1. Analytical results of five lots from non-consecutive batches (Appendix I) indicate that the product consistently meets these specifications. The major components of Superba™ Krill Oil are triglycerides and phospholipids high in omega-3 fatty acids such as EPA (C 20:5 n-3 fatty acid) and DHA (C 22:6 n-3 fatty acid). The maximum amount of EPA + DHA present in Superba™ Krill Oil will be 23.5 ± 2 g/100 g of the oil. No processing aids or additives, with the exception of residual amounts of ethanol solvent, are included in the final Superba™ Krill Oil product. Likewise due to naturally occurring astaxanthin esters that aid in its preservation, addition of an exogenous antioxidant is not required. Based on an 18 month stability test at different storage temperatures, the shelf life of Superba Krill Oil is set to 18 months when stored at 2-8°C. The results of pesticides and other environmental contaminants including PCBs, dioxins, furans and dioxin like PCBs, organochlorine pesticides, PBDEs, PAHs, and elements and heavy metal analyses from multiple batches of the product are presented in Appendix II.

Table 1. Typical compositional analysis and specifications of Superba™ Krill Oil

Parameter	Limits	Assay method
Appearance	Dark red viscous oil	Visual
Lipid composition		
Total phospholipids (g/100 g)	43 ± 3	N A88 ¹ /AM-AKMB-012
- Omega-3 phospholipids of total PL ² % (w/w)	>70	Calculation
Triglycerides (g/100 g)	<50	N A88 ¹ /AM-AKMB-012
Fatty acid profile		
Total omega-3 (expressed as g/100 g)	23.5 ± 2	AOCS Ce 1b-89/AM-ABM-013
-C 20:5 n-3 (EPA)(expressed as g/100 g)	14 ± 2	AOCS Ce 1b-89/AM-ABM-013
-C 22:6 n-3 (DHA)(expressed as g/100 g)	6.5 ± 1	AOCS Ce 1b-89/AM-ABM-013
Total omega-6	<3.0	AOCS Ce 1b-89/AM-ABM-013
Stability index		
Peroxide value (mEq peroxide/kg)	<2	AOCS Cd 8b-90/AM-058
Antioxidants		
Astaxanthin ⁴ (mg/kg)	100 ± 20 (minimum)	N A23 ³ /AM-ABM-011
Water and Ethanol		
Water activity at 25°C	<0.5	AOAC 978.18
Ethanol content (% w/w)	<3.0	GC
Microbiology		
Total plate count (cfu/g)	<2500	NF EN ISO 4833/CQ-MO-231
<i>E. coli</i> (1 sample at 10 g)	Negative	Petrifilm Select EC
Coliform bacteria, 37°C (cfu/g)	<10	NordVal Ref. No. 014
<i>Salmonella</i> negative (PCR) (1 sample at 10 g)	Negative	AES 10/4-025/04
Mold and Yeast (cfu/g)	<10	NordVal Ref. No. 016

¹Based on Homan and Anderson (1998) and Moreau (2006)

²Omega-3 phospholipid: defined as phospholipid where on average one out of two possible positions is occupied by an omega-3 fatty acid.

³Based on Schierle J. & Härdi W. (1994); ⁴Expressed as astaxanthin diols.

000006

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.