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ORIGINAL SUBMISSION

GRAS ASSOCIATES, LLC

Generally Recognized As Safe

20482 Jacklight Lane Bend, OR 97702-3074 541 678-5522
mcquate@gras-associates.com www.gras-associates.com



January 18, 2008

01-24-08 A11:35 OUT

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety (HFS-200)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Attention: Dr. Robert L. Martin

Dear Dr. Martin:

On behalf of Neptune Technologies & Bioresources of Laval (Quebec), Canada, we are submitting for FDA review a GRAS notification for High Phospholipid Krill Oil. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance as discussed in the GRAS guidance document.

As part of the deliberations by our Expert Panel on the safety of the subject krill oil as a human food ingredient, two unpublished scientific studies were considered. They have been included as Appendix G in the submission. Even though each of the reports is identified as being confidential, we recognize that the content submitted cannot be held as confidential, and we hereby waive the designation of confidentiality.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via telephone or email.

We look forward to your feedback.

Sincerely,

Robert S. McQuate, Ph.D.
CEO & Co-Founder
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074
541-678-5522
mcquate@gras-associates.com
www.gras-associates.com

Enclosure: GRAS Notification – High Phospholipid Krill Oil (in triplicate)

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I. GRAS EXEMPTION CLAIM

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

High phospholipid krill oil, meeting the specifications described below, has been determined to be Generally Recognized As Safe (GRAS), in accordance with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination was made by experts qualified by scientific training and experience; it is based on scientific procedures as described in the following sections; and the evaluation accurately reflects the conditions of the ingredient's intended use in foods.

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Signed:

January 18, 2008

Date

Robert S. McQuate, Ph.D.
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074

B. Name and Address of Notifier

Neptune Technologies and Bioresources
2740 Pierre Peladeau Avenue, Suite H200
Laval (Quebec)
Canada H7T 3B3

As the notifier, Neptune Technologies and Bioresources ("Neptune") accepts responsibility for the GRAS determination that has been made for high phospholipid krill oil as described in the subject notification; consequently, high phospholipid krill oil meeting the conditions described herein is exempt from pre-market approval requirements for food ingredients.

C. Common Name and Identity of the Notified Substance

High phospholipid krill oil; also see Sections II.A and II.B.

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1. 21 CFR 170.36(c)(1) (1/7/07)

D. Conditions of Intended Use in Food

High phospholipid krill oil is intended to be added as a substitute or alternative to fish oils to the following food categories at per serving levels ranging from 150 – 500 mg: non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk products; processed fruits/fruit juices; and medical foods. The maximum daily consumption of the subject krill oil will provide up to 2.2 g/person/day of EPA and DHA.

E. Basis for the GRAS Determination

Pursuant to 21 CFR § 170.30, high phospholipid krill oil has been determined to be GRAS on the basis of scientific procedures as discussed in the detailed description provided below.

F. Availability of Information

The data and information that serve as the basis for this GRAS Notification will be sent to the US Food and Drug Administration (FDA) upon request or will be available for review and copying at reasonable times at the offices of GRAS Associates, LLC, located at 20482 Jacklight Lane, Bend, OR 97702-3074.

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II. CHEMISTRY AND MANUFACTURE OF NKO™

NKO™ is refined krill oil which is derived from the marine organism, *Euphasia superba*, which is harvested from Antarctic waters. Krill is recognized as a vital part of the marine food chain for baleen whales, mantas, whale sharks, crabeater seals and other seals, and a few seabird species.

The following description of krill is given on Neptune's website.²

"Krill is a generic term used to designate all deepwater marine planktonic crustacean species. It looks like miniature shrimp, ranging between one and six centimeters in length. These 85 species represent the planet's most abundant animal biomass found in banks that may extend over several square kilometers. Krill fisheries can mainly be found in two ocean regions: the Antarctic Ocean and the North Pacific Ocean, along the Canadian and Japanese coasts. According to a World Health Organization estimate, the total quantity of krill in these two oceans exceeds 500 million tons. Approximately 110,000 tons of krill are harvested every year, or about less than one-half of 0.1% of the existing resources."

NKO™ is a whole lipid extract and is an opaque reddish oil with a seafood odor. The major components of NKO™ are triglycerides and phospholipids which are rich in eicosapentaenoic acid (EPA, C20:5 n-3 fatty acid) and docosahexaenoic acid (DHA, C22:6 n-3 fatty acid). NKO™ is an oil intended for use as a dietary ingredient as a source of omega-3 fatty acids, which as noted are found in NKO™ in their phospholipid form. No processing aids or additives are included in the final NKO™ product due to naturally occurring antioxidants that aid in NKO™'s preservation. Additionally, no proprietary or coloring ingredients are added to the oil from Antarctic krill to produce NKO™.

A. Common or Usual Name of the Subject Material

High phospholipid krill oil is the common or usual name of the material that is the subject of the GRAS evaluation. The specific substance evaluated is Neptune Krill Oil™, which is commonly referred to throughout this evaluation as NKO™. As noted in the preceding paragraph, NKO™ is a mixture of triglycerides and phospholipids that contain numerous constituent fatty acids. The compositional character of NKO™ is described in detail in this Section.

B. Manufacturing and Specifications for NKO™

1. Krill Source and Handling

NKO™ is extracted from *Euphasia superba*. The current taxonomic placement of *Euphasia superba* is summarized below:

² <http://www.neptuneoil.com/krill.html>

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