SUPERBA*Krill*®

# Superba™ Krill Oil
# US Claims Substantiation Dossier

AkerBioMarine™
Antarctic US

SUPERBA*Krill*®

# What can you say about Superba™ Krill in the U.S. market?

**Aker BioMarine is the largest vertically integrated krill oil supplier in the world. It offers krill-based products to the dietary supplement, pet nutrition and aquaculture markets worldwide. These products are produced through a sustainable and traceable value chain that is owned and controlled by Aker BioMarine. Its flagship krill oil brand – Superba™ – is the most clinically researched krill ingredient in the world today.**

Superba™ Krill is a unique source of the long chain omega-3 fatty acids EPA and DHA, as well as phospholipids, choline and astaxanthin. Because of its uniqueness in the omega-3 category, there are several claim opportunities companies can use to position and differentiate their product(s) in a crowded marketplace.

As each region has its own unique set of regulations, it is important to know which claims are relevant in your market. To help guide you, we have created this comprehensive reference tool, which provides a variety of suggested claims that can be used when promoting Superba™ Krill products* in the U.S. market.

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*The information provided in this document is for educational purposes only. Aker BioMarine does not make any representation as to the permissibility of the statements contained herein for use on finished product marketing materials. Importantly, finished product claims must be evaluated in light of the finished product marketing as a whole, which includes but is not limited to advertising, the product label, and other labeling. Aker BioMarine recommends that you seek the advice of competent legal counsel prior to incorporating any claims into your company's marketing materials.

## CLAIM CATEGORIES FOR SUPERBA™ KRILL OIL

| TABLE 1: Claims | Daily Dose Recommended for Superba™ 2 | Daily Dose Recommended for Superba™ Boost | Page |
|---|---|---|---|
| General | 0.3-1 gram | 0.3-1 gram | 5 |
| Sustainability/Environmental | 0.3-1 gram | 0.3-1 gram | 5 |
| Uptake/Bioavailability | 0.3-2 grams | 0.3-2 grams | 6 |
| Nutrient Content Claims | ≥ 1.1 grams | ≥ 1.1 grams | 6 |
| Qualified Health Claims | ≥ 1.4 grams | ≥ 0.8 grams | 7 |
| **Claims for Effect** | | | |
| Cardiovascular Health | ≥ 1.4 grams | ≥ 1.1 grams | 6 |
| Sports Nutrition/Exercise | 2 grams | 2 grams | 6 |
| Brain & Eye Health | 2 grams* | 2 grams* | 6 |
| Liver Health | from 1.7 grams | from 1.2 grams | 6 |

*2 grams of Superba™ 2 deliver 44% of the daily intake of DHA needed to obtain the beneficial effect; 2 grams of Superba™ Boost deliver 56% of the daily intake of DHA needed to obtain the beneficial effect.

# GENERAL BACKGROUND INFORMATION ON KRILL OIL

### Characteristics of Krill Oil

Krill feed on marine algae that produce the essential omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are integrated into the krill bodies. Thus, these omega-3 fatty acids can be extracted in oil, carrying with them other beneficial components such as phospholipids, choline, and astaxanthin [1-3]. It is this particular combination of elements that makes krill oil unique in the omega-3 market *(see Table 2)*.

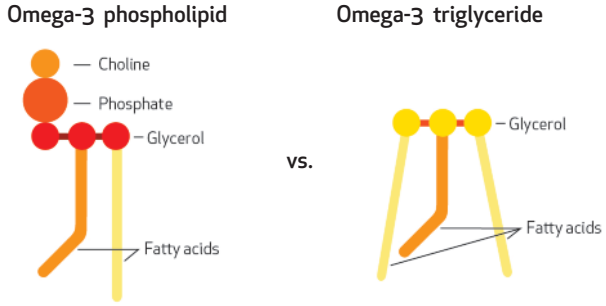
**TABLE 2: Krill Oil is Naturally Rich in Essential Nutrients**

| KRILL OIL INGREDIENTS | CHARACTERISTICS |
|---|---|
| **1) Omega-3 Fatty Acids (EPA & DHA)** | A particular class of fatty acids that are found in fat and cell membranes and can be used as energy. |
| **2) Phospholipid** | A lipid consisting of a phosphate, a glycerol group and two fatty acids. Phospholipids represent the building blocks of all cell membranes and therefore effectively deliver EPA and DHA to the blood, tissues and organs. |
| **3) Choline** | It is important for the synthesis of neurotransmitters (acetylcholine) and phospholipids. It is also crucial for transporting lipids and reducing homocysteine levels. |
| **4) Astaxanthin** | This carotenoid has potent antioxidant properties and protects the omega-3s fatty acids in krill oil from oxidation, keeping them naturally fresh and stable over time. |

In krill oil, the majority of the omega-3 fatty acids are bound to a particular type of fat called a phospholipid [4], whereas in other marine oils these omega-3 fatty acids are bound to other forms of fat such as triglycerides. While triglycerides consist of three fatty acids bound to a glycerol backbone, phospholipids have two fatty acids and instead of the third fatty acid a phosphorus group is linked to a head group, such as choline *(see Figure 1)* [5].

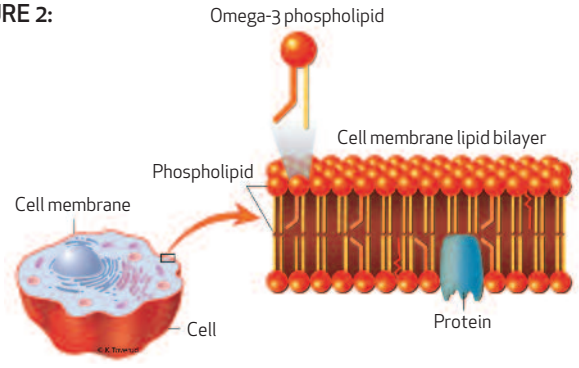
**FIGURE 1:**

**Structural Differences between Phospholipids and Triglycerides**




Due to this arrangement of a hydrophilic (water-loving) head group and hydrophobic (water-hating) fatty acid tails, phospholipids have the ability to mix with water and form two parallel layers. This bilayer is formed in such a way that the hydrophilic heads are on the outer side, while the hydrophobic tails are in the inside *(see Figure 2)*.

**FIGURE 2:**




This phospholipid bilayer formation is the basis for all life since it forms cell membranes common to all animals. Thus, if the omega-3 fatty acids are given in phospholipid form, they can readily be integrated into cell membranes. There they regulate membrane fluidity, which is important for the correct functioning of membrane proteins and the transmission of signals over the membrane. Omega-3 fatty acids can also be released from the cell membrane into the cell, where they influence which proteins are made and, ultimately, specific cellular functions.

The difference in the chemical structure of omega-3 fatty acids in either phospholipid or triglyceride form may be important, since several animal studies have shown that EPA and DHA from phospholipids are more effectively incorporated into cells and tissues compared to EPA and DHA from triglycerides [6-9].

The delivery form of these fatty acids might therefore dictate how these fats are incorporated in tissues and used by the body.

### Antarctic Krill *(Euphausia superba)*

Krill oil is extracted from Antarctic krill, a small shrimp-like crustacean that lives in the Southern Ocean. With an estimated 500 million metric tons of krill in Antarctic waters, it represents the largest marine biomass on earth (*Deep Sea Research, 2009*).

### EPA & DHA

EPA and DHA play many roles in the human body. Among other functions, they promote a healthy heart, and help maintain normal triglyceride and blood pressure levels. DHA in particular also contributes to normal brain function and eye health. DHA is further important for children in that it contributes to eye development in the fetus and to normal visual development of infants. Since the human body cannot efficiently make EPA and DHA on its own [11], it is important that these fatty acids are supplied through the diet.

### Choline

In addition to EPA and DHA, krill oil also supplies choline in the form of phosphatidylcholine. Choline is a conditionally essential nutrient [12], which is needed for the synthesis of neurotransmitters (acetylcholine) and phospholipids. It is also important for transporting lipids and reducing homocysteine levels. The human body can make choline, but not in sufficient amounts; the rest needs to be obtained from the diet.

Acute deficiencies may lead to fatty liver and muscle damage risk [14]. In the US, data show that 90% of Americans have an inadequate intake of choline, according to the Choline Information Council. Supplementing the diet with krill oil contributes to choline intake, which in turn supports cell membrane function and contributes to normal liver function, as well as normal lipid and homocysteine metabolism.

## WHAT IS A CLAIM?

Generally speaking, a claim is any label statement pertaining to a product's characteristics. Claims are voluntary, and must be true and substantiated by competent and reliable scientific evidence, either by literature or by product-specific information that can be produced if required.

If a claim relates in any way to prevention, reduced risk of a disease or condition-specific health benefits due to the food or its constituents, it is a **health claim**. As such, it is subject to premarket review and authorization by FDA. Health claims can be authorized based on either an extensive review of scientific literature or on an "authoritative statement" from certain scientific bodies of the U.S. Government or the National Academy of Sciences.

When there is emerging evidence for a relationship between a food substance (a food, food component, or dietary ingredient) and reduced risk of a disease or health-related condition, but the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation, the **qualified health claim** petition process provides a mechanism to request that FDA review the scientific evidence and exercise enforcement discretion to permit the use of the qualified claim in food labeling.

If a claim is nutrition-related, e.g. "rich-in", "source of", it is considered a **nutrient content claim** and only permitted on the label if authorized by FDA. These claims have to be substantiated by the product's characteristics. For example, a product can only claim it is a "Good Source of Choline" if the product contains at least 55 mg of choline per serving.

**Structure-function claims** describe the role of a nutrient or dietary ingredient and how it intends to affect the normal structure and/or function of the human body. For example, "Choline serves as a precursor for acetylcholine which is involved in skeletal muscle innervation and muscle control." Structure/ function claims cannot explicitly or implicitly link the claimed effect to a disease or state of health leading to disease.

Structure-function claims are not pre-approved by FDA, but the manufacturer must have substantiation that the claim is truthful and not misleading and must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease."

# CLAIMS FOR SUPERBA™ KRILL OIL

*(Applies to ALL Superba™ products with a recommended dosage range of 0.3-1 gram, unless otherwise specified)*

### General Claims:

- No fishy aftertaste*
- Easy-to-swallow softgel*
- Small, red and powerful
- Significantly increases the omega-3 index
- Next generation omega-3
- One of the cleanest omega-3 oils from marine sources
- From the icy, deep, cold Antarctic waters
- From Antarctic krill
- No odor or aftertaste*
- Harvested according to Norwegian fishing tradition
- Norwegian Innovation
- Made in the USA
- Produced using a patented & exclusive technology called Flexitech™
- Proud Supporter of the Omega-3 Index Project™
- NSF® GMP Manufactured
- Produced through a value chain that is 100% owned and controlled by Aker BioMarine

*(See also references 10 & 15 for documentation.)*

**Aker BioMarine-Discovery Research Consumer Study, 2012*

### Superba™ 2 Claims:

*(Applies to all Superba™ 2 products with a recommended dosage range of 0.3-1 gram)*

SUPERBA2™

- New & Improved
- Produced using a patented & exclusive technology called Flexitech™
- Made in the USA
- Enhanced encapsulation properties
- Improved smell and taste
- Certified 100% sustainable and traceable
- Produced through a vertically integrated supply chain that is 100% owned and controlled by Aker BioMarine

*(Documentation provided upon request.)*

### Superba Boost Claims:

*(Applies to all Superba™ Boost products with a recommended dosage range of 0.3-1 gram)*

SUPERBA*Boost*™

- More concentrated
- Produced using a patented & exclusive technology called Flexitech™
- Made in the USA
- Improved smell and taste
- More phospholipids and choline
- Certified 100% sustainable and traceable
- Produced through a vertically integrated supply chain that is 100% owned and controlled by Aker BioMarine

*(Documentation provided upon request.)*

### Sustainability/Environmental Claims:

- Certified sustainable source of omega-3s EPA & DHA
- Produced using Eco-Harvesting® Technology
- Virtually mercury-free*
- 100% traceable back to the exact position where the krill was harvested (confirmed by GPS)
- MSC-certified (MSC ecolabel)**
- Naturally non-GMO
- Non-GMO Project Verified***
- Antarctic Wildlife Research Fund (AWR) Supporter****

* Below the limit of quantification (< 0.005 mg/kg)

** An Ecolabel License Agreement is required for displaying the MSC ecolabel on the product. Businesses in the supply chain must also undertake a traceability audit to meet the MSC Chain of Custody Standard.

*** A separate agreement for Non-GMO status must be signed and supply chain approved through the Non-GMO Project. Businesses in the supply chain must also undertake a traceability audit to meet the Non-GMO Project's Chain of Custody Standard.

**** Separate agreement with AWR required.

# STRUCTURE-FUNCTION CLAIMS:

### Uptake/Bioavailability Claims:

*(Applies to Superba™ 2 products with a recommended dosage range of 0.3 to 2 grams; Applies to Superba™ Boost products with a recommended dosage range of 0.3- 2 grams)*

- Documented to Raise the Omega-3 Index
- Significantly improves the omega-3 levels in your body in just 30 days
- Krill oil significantly improves your Omega-3 Index
- Krill oil helps/improves/fights/overcome omega-3 deficiency
- High incorporation of EPA and DHA into the body's cells
- High uptake of EPA and DHA into the cells
- Recommended to consume fish twice a week – if you don't, this product will help you reach the desired EPA and DHA levels in your body

  *(See also references 10 & 15 for documentation.)*

### Cardiovascular Health:

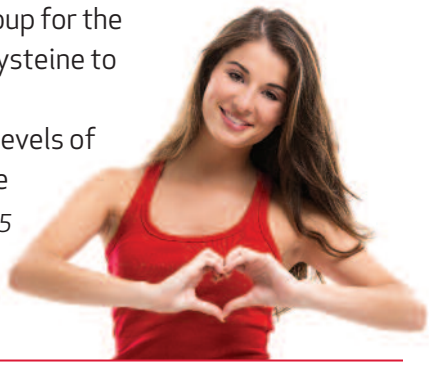
*(Applies to all Superba™ 2 products with a starting dosage of 1.4 grams; Applies to all Superba™ Boost products with a starting dosage of 1.1 grams)*

- EPA and DHA help contribute to the normal function of the heart

  *(See also references 16 & 21 for documentation.)*

- Choline is oxidized in the body to form betaine, which provides a methyl group for the conversion of homocysteine to methionine
- May help reduce the levels of plasma homocysteine

  *(See also references 22 -25 for documentation.)*



### Sports Nutrition/Exercise:

*(Applies to all Superba™ 2 products with a starting dosage of 2 grams; Applies to all Superba™ Boost products with a starting dosage of 2 grams)*

- Krill oil supplementation may augment post-exercise immune function in young adults
- Krill oil may support immune function in young adults after heavy exercise

  *(See also reference 26 for documentation.)*

### Brain & Eye Health*:

*(Applies to all Superba™ 2 products with a recommended dosage range of 1-2 grams; applies to all Superba™ Boost products with a recommended dosage range of 1-2 grams)*

- DHA contributes to maintenance of normal brain function
- DHA contributes to the maintenance of eye health

  *(See also references 16, 27, 28 for documentation.)*

- A new study has identified phospholipids as the major transporter for DHA uptake into brain

  *(See also reference 29 for documentation.)*

**To obtain the claimed benefit the required dose is 250 mg DHA; 2 grams of Superba 2 delivers 44% of DHA needed to obtain the claimed effect (for brain and eye health); 2 grams of Superba Boost delivers 56% of DHA needed to obtain the claimed effect (for brain and eye health).*

### Liver Health:

*(Applies to all Superba 2 products with a starting dosage of 1.7 grams) grams; applies to all Superba™ Boost products with a starting dosage of 1.2 grams)*

- Choline is a required component of Very Low Density Lipoproteins (VLDL); these lipoproteins help transport fat and cholesterol away from the liver through the blood to the tissues that require them
- May promote healthy liver function
- Contributes to normal lipid metabolism

  *(See also references 14,23,30-34 for documentation.)*

# NUTRIENT CONTENT CLAIMS:

- "Good" source of choline *(> 55 mg choline)*
  - *To use this claim for Superba™ 2 products, the recommended dosage range is 1.1 grams krill oil or more; for Superba™ Boost products, the dosage range is 0.8 grams of krill oil or more*
- "Excellent" source of choline (> 110 mg choline);
  - To use this claim for Superba™ Krill 2 products, the recommended dosage range is 2.2 grams krill oil or more; for Superba™ Boost products, the dosage range is 1.6 grams or more
- Omega-3, phospholipid and choline, naturally preserved by astaxanthin
- Omega-3 lecithin with choline, naturally preserved by astaxanthin
- Krill oil with omega-3 phospholipids provides the omega 3-fatty acids EPA and DHA, and the nutrient choline

# QUALIFIED HEALTH CLAIM

The following is the current qualified health claim* for the omega-3s EPA and DHA:

***"Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]"***

*(To meet the Qualified Health Claim, the recommended dosage for Superba™ 2 is 1.4 grams; the recommended dosage for Superba™ Boost is 1.1 grams)*

*A Qualified Health Claim is subject to enforcement discretion by FDA

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