

## NATURAL HEALTH PRODUCT

### KRILL OIL

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

#### Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

**Date** September 25, 2018

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
Krill oil	Krill oil	<ul style="list-style-type: none"> <li>▶ <i>Euphasia pacifica</i></li> <li>▶ <i>Euphausia superba</i></li> </ul>	Whole

References: Proper name: US FDA 2008, Bunea et al. 2004, Takaichi et al. 2003; Common name: US FDA 2008, Bunea et al. 2004, Takaichi et al. 2003; Source materials: US FDA 2008, Bunea et al. 2004, Takaichi et al. 2003.

#### Route of administration

Oral

#### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

## Use(s) or Purpose(s)

- ▶ Source of EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) for the maintenance of good health (Batetta et al 2009; US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003; IOM 2002).
- ▶ Source of omega-3 fatty acids for the maintenance of good health (Batetta et al 2009; US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003; IOM 2002).
- ▶ Source of the omega-3 fatty acids such as EPA and DHA (Batetta et al 2009; US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003; IOM 2002).

## Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

Method of preparation: Standardized fixed oil

Not to exceed 4.1 grams of krill oil, per day; providing 100 milligrams or more eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) per day (US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003; IOM 2002).

### Direction(s) for use

No statement required.

### Duration(s) of use

No statement required.

## Risk information

### Caution(s) and warning(s)

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

### **Contraindication(s)**

No statement required.

### **Known adverse reaction(s)**

Stop use if hypersensitivity/allergy occurs (HC 2009).

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### **Storage conditions**

*All products*

Store in airtight container, protected from light (Ph.Eur. 2012; USP 35 2012).

*All products, except those encapsulated*

Refrigerate after opening (Wille and Gonus 1989).

### **Specifications**

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.
- ▶ Peroxide, anisidine, and totox values of krill oil or omega-3 fatty acids derived from krill oil must be in accordance with the methods set out by the Association of Analytical Community (AOAC) and/or Pharmacopoeial analytical methods. These specifications are necessary to ensure the oxidative stability of the krill oil and the omega-3 fatty acids from krill oil (HC 2007). The maximum peroxide value (PV) must be 5 mEq/kg, the maximum anisidine value (AV) must be 20 while the maximum Totox value must be 26 (calculated as  $2 \times PV + AV$ ).
- ▶ The dioxins, polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs); the dioxin-like polychlorinated biphenyls (DL PCBS); and the polychlorinated biphenyls (PCBs) are contaminants in oils from marine sources. Testing for these contaminants is required. Testing should be performed using appropriate analytical methods, such as method No. 1613 revision B of the Environmental Protection Agency for PCDDs and PCDFs and method No. 1668B of the Environmental Protection Agency for

chlorinated biphenyl congeners (Ph. Eur: EPA 2008; EPA 1994). Licence holders are advised to consult the Commission of the European Communities documents on dioxins and dioxin-like PCB contaminants in marine oil for further information (EU 2006a,b; EU 2001). Refer to Section 3.3.8 of the Quality of Natural Health Products Guide for more information on the acceptable limits of dioxins and dioxin-like PCBs.

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