Health Canada Santé Canada

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date July 4, 2012

Proper name(s)

Krill oil (US FDA 2008; Bunea et al. 2004; Takaichi et al. 2003)

Common name(s)

Krill oil (US FDA 2008; Bunea et al. 2004; Takaichi et al. 2003)

Source material(s)

Euphausia spp. (Euphausiidae) - Whole (US FDA 2008; Bunea et al. 2004; Takaichi et al. 2003)

Route(s) of administration

Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)

Statement(s) to the effect of:

- Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) 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).

Dose(s)

Subpopulation(s)

Adults (≥ 19 years)

Quantity(ies)

Maximum dosage of 4.1 g krill oil, per day (US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003) containing at least 100 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) (IOM 2002).

Directions for use

No statement required.

Duration of use

No statement required.

Risk information

Statement(s) to the effect of:

Caution(s) and warning(s)

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Hypersensitivity/allergy has been known to occur with shellfish; if this occurs, discontinue use (HC 2009).

Storage conditions

Statement(s) to the effect of:

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

All products, except those encapsulated:
Refrigerate after opening (Wille and Gonus 1989).

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

Specifications

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- 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). Refer to Table 1 below.
- 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 are required and must be performed using either the analytical method of the European Commission Regulation EU 252/2012 (EU 2012) or the U.S. Environmental Protection Agency's method 1613B for PCDDs and PCDFs and method 1668A for PCBs (USP 35; US EPA 2010, 2008,1994). Applicants are advised to consult the Council of the European Union document on these contaminants for further information (EU 2011). Refer to Table 2 below.

Table 1 Maximum values of oxidative stability parameters for krill oil (HC 2007)

Oxidative stability parameter	Maximum value
Peroxide value (PV)	5 mEq/kg
p-Anisidine value (AV)	20
Totox value	26 (calculated as (2 x PV) + AV)

Table 2 Maximum levels of dioxins, dioxin-like polychlorinated biphenyls (DL PCB) and polychlorinated biphenyls (PCB) in oils from marine sources

Dioxin, DL PCB, and PCB contaminants	Maximum level	
	EU 1259/2011	USP 35
Dioxins (sum of PCDDs + PCDFs)[1,2]	1.75 pg/g	1.0 pg/g
Sum of dioxins and DL PCBs[1,3]	6 pg/g	
PCBs[4]	200 ng/g	0.5 ppm[5]

1. Expressed in World Health Organization (WHO) toxic equivalents using WHO-toxic equivalent factors (TEFs). Analytical results relating to 17 individual dioxin congeners of toxicological concern are expressed in a single quantifiable unit: 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) toxic equivalent concentration (TEQ) (USP 35; EU 2011).
2. Sum of dioxins: WHO-PCDD/F-TEQ (USP 35; EU 2011)
3. Sum of dioxins and dioxin-like PCBs: WHO-PCDD/F-PCB-TEQ (EU 2011)
4. Sum of PCB congeners 28, 52, 101, 118, 138, 153 and 180 (USP 35; EU 2011)
5. Equivalence: 0.5 ppm = 500 ng/g

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