Health Canada Santé Canada

NATURAL HEALTH PRODUCT

SEAL 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.

There are many *N*-3 polyunsaturated fatty acids, popularly known as omega-3 acids/ω-3 fatty acids (Ph.Eur. 2012). This monograph is specific to eicosapentaenoic acid (C20:5 n-3; EPA), docosahexaenoic acid (C22:6 n-3; DHA) and docosapentaenoic acid (C22:5 n-3; DPA).

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)
Seal oil	Seal oil	▸ *Cystophora cristata* ▸ *Erignathus barbatus* ▸ *Halichoerus grypus* ▸ *Pagophilus groenlandicus* ▸ *Phoca vitulina* ▸ *Pusa hispida*	Blubber

References: Proper name: NHPID, Brox et al. 2001,Østerud et al. 1995; Common name: Brox et al. 2001, Østerud et al. 1995; Source materials: ITIS 2012, MMR 2011, EC 2011, 2008.

The seal population is not required to be identified on the label, but the population must be identified on the Animal Tissue Form (ATF) when the source material is oil from seals from Quebec populations.

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 by age group:

Children 1-2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006).

Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006).

Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

Products providing 100-3000 milligrams of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA), per day

- Source of omega-3 fatty acids for the maintenance of good health (FCC 8 2012; Wu et al. 2012; Simopoulos 2007; Oh 2005; Brox et al. 2001; Simopoulos 1999).
- Source of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA) for the maintenance of good health (FCC 8 2012; Wu et al. 2012; Simopoulos 2007; Oh 2005; Brox et al. 2001; Simopoulos 1999).

Products providing 150-2000 milligrams of EPA, DHA and DPA; including 150 milligrams or more DHA, per day (maximum doses of EPA + DHA in Table 1 below apply)

Helps support (healthy) development of the brain/(and), eyes/(and) nerves in children up to 12 years of age (FCC 8 2012; Ryan and Nelson 2008; Marszalek and Lodish 2005; Haag 2003; Giedd et al. 1999; Mills 1999).

Products providing 1000-3000 milligrams of EPA, DPA and DHA; including 340 milligrams or more EPA, per day and having a ratio of EPA: DPA: DHA between 1-1.5:1:1.5-2

- Helps to reduce serum triglycerides/triacylglycerols (Mann et al. 2010; Meyer et al. 2009).

- Helps reduce serum triglycerides and support cardiovascular health (Mann et al. 2010; Meyer et al. 2009; WHO/FAO 2003).

Products providing 200-3000 milligrams of EPA, DPA and DHA and having a ratio of EPA: DPA: DHA between 1-1.5:1:1.5

Helps support cardiovascular health (Mann et al. 2010; Meyer et al. 2009; WHO/FAO 2003).

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Method of preparation: Standardized fixed oil

Note
Potency must be expressed as the quantity (mg) and/or percent (%) of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA) (% w/w) relative to the total quantity of seal oil.

Table 2: Daily doses for eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA) in seal oil.

Subpopulation(s)		EPA + DHA + DPA (mg/day)	
		Minimum[1]	Maximum[2]
Children	1-8 years 9-11 years	100 100	1500 2000
Adolescents	12-13 years 14-17 years	100 100	2000 2500
Adults[3]	18 years and older	100	3000

[1] Restrictions to minimum dose may apply according to Use(s) or Purpose(s) section above.

[2] Adult maximum dose is supported by National Heart Foundation of Australia 2008. Children and adolescent maximum doses, calculated as a fraction of the adult dose, are relative to body weight and caloric intake.

[3] Includes pregnant and breastfeeding women.

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

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 seal oil or omega-3 fatty acids derived from seal 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 seal oil and the omega-3 fatty acids from seal oil (HC 2013b). 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 X PV + AV).
- The dioxins, polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs); the dioxin-like polychlorinated biphenyls (dioxin-like 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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