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

Date: July 18, 2017

Proper name(s):
Seal oil (NHPID; Brox et al. 2001; Østerud et al. 1995)

Common name(s):
Seal oil (Brox et al. 2001; Østerud et al. 1995)

Source material(s):
Oil from the blubber of one or more of the following species (MMR 2011) in its natural triglyceride/triacylglycerol form and/or its concentrated esterified form

Bearded seal (Erignathus barbatus) (ITIS 2012)
Gray seal (Halichoerus grypus) (ITIS 2012)
Harbor seal (Phoca vitulina) (ITIS 2012), except the Phoca vitulina mellonae of the Lac des Loups Marins population (EC 2011, 2008)
Harp seal (Pagophilus groenlandicus, synonym: Phoca groenlandica) (ITIS 2012)
Hooded seal (Cystophora cristata) (ITIS 2012)
Ringed seal (Pusa hispida, synonym: Phoca hispida) (ITIS 2012)
Notes
The term “blubber” and the organism’s Latin binomial must be indicated on the PLA and label as source material information, e.g., “Pagophilus groenlandicus blubber”.
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(s) of administration:
Oral

Dosage form(s):
This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:

- **Children 1-2 years**: The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

Use(s) or Purpose(s):
For products providing 100-3000 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) + docosapentaenoic acid (DPA), per day

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

For products providing 150-2000 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) + docosapentaenoic acid (DPA) including at least 150 mg DHA, per day (maximum doses of EPA + DHA in Table 1 below apply)
Helps to support the development of the brain, eyes and nerves in children up to 12 years of age (Ryan and Nelson 2008; Marszalek and Lodish 2005; Haag 2003; FCC 7; Giedd et al. 1999; Mills 1999).

For products providing 1000-3000 mg eicosapentaenoic acid (EPA) + docosapentaenoic acid (DPA) + docosahexaenoic acid (DHA) + including at least 340 mg EPA, per day and having a ratio of Eicosapentaenoic acid (EPA): Docosapentaenoic acid (DPA): Docosahexaenoic acid (DHA) between 1-1.5:1:1.5-2

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

For products providing 200-3000 mg Eicosapentaenoic acid (EPA) + Docosapentaenoic acid (DPA) + Docosahexaenoic acid (DHA) and having a ratio of Eicosapentaenoic acid (EPA): Docosapentaenoic acid (DPA): Docosahexaenoic acid (DHA) between 1-1.5:1:1.5


**Dose(s):**

**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 1:** Daily dose for eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) + docosapentaenoic acid (DPA) in seal oil

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>EPA + DHA + DPA (mg/day)</th>
<th>Minimum&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Maximum&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td></td>
<td>100</td>
<td>1500</td>
</tr>
<tr>
<td>Adolescents</td>
<td></td>
<td>100</td>
<td>2000</td>
</tr>
<tr>
<td></td>
<td>14-17 y</td>
<td>100</td>
<td>2500</td>
</tr>
<tr>
<td>Adults&lt;sup&gt;3&lt;/sup&gt;</td>
<td>≥ 18 y</td>
<td>100</td>
<td>3000</td>
</tr>
</tbody>
</table>

<sup>1</sup> Restrictions to minimum dose may apply according to Use(s) or Purpose(s) section above.

<sup>2</sup> 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.

<sup>3</sup> Includes pregnant and breastfeeding women.

**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.

**Storage conditions:**

*For all products*

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

*For all products, except those encapsulated*

Refrigerate after opening (Wille and Gonus 1989).

**Non-medicinal ingredients:**

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

**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). Refer to Table 2 below.
- 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 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 3 below.

**Table 2**: Maximum values of oxidative stability parameters for seal oil (HC 2013)

<table>
<thead>
<tr>
<th>Oxidative stability parameter</th>
<th>Maximum value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroxide value (PV)</td>
<td>5 mEq/kg</td>
</tr>
<tr>
<td>p-Anisidine value (AV)</td>
<td>20</td>
</tr>
<tr>
<td>TOTOX value</td>
<td>26 [calculated as (2 x PV) + AV]</td>
</tr>
</tbody>
</table>

**Table 3**: Acceptable limits of dioxins and dioxin-like polychlorinated biphenyls in oils from marine sources

<table>
<thead>
<tr>
<th>Dioxin and dioxin-like polychlorinated biphenyl contaminants</th>
<th>Maximum level $^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sum of PCDDs + PCDFs</td>
<td>2.0 pg TEQ TEF/g oil</td>
</tr>
<tr>
<td>Sum of dioxins and dioxin-like PCBs $^2$</td>
<td>10.0 pg TEQ TEF/g oil</td>
</tr>
</tbody>
</table>

$^1$ 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 or TEQ (EU 2006).

$^2$ The dioxin-like PCBs that can be determined by Method 1668B are the 12 PCBs designated as toxic by WHO: congeners 77, 81, 126, 169, 105, 114, 118, 123, 156, 157, 167, and 189 (EPA 2008; EU 2006).

**References cited:**


Seal oil


References reviewed:


docosahexaenoic acids on lipid metabolism, eicosanoid production, and platelet aggregation in hypercholesterolemic rats. Lipids 33(9):897-904.


Murphy MG, Wright V, Ackman RG, Horackova M. 1997. Diets enriched in menhaden fish oil, seal oil, or shark liver oil have distinct effects on the lipid and fatty-acid composition of guinea pig heart. Molecular and Cellular Biochemistry 177(1-2):257-269.
