

NATURAL HEALTH PRODUCT

FISH 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. 2023). This monograph is specific to eicosapentaenoic acid (C20:5 n-3; EPA) and docosahexaenoic acid (C22:6 n-3; DHA).

Notes

- This monograph only covers naturally-occurring fatty acids in fish oil with both EPA and DHA. Fish oils can be concentrated but not spiked with additional fatty acids.
- 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

March 28, 2024

Proper name(s), Common name(s), Source information

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

Proper name(s)	Common name(s)	Source information	
		Source material(s) ¹	Part(s)
Fish oil	Fish oil	 Ammodytidae Carangidae Clupeidae Engraulidae Gadidae² Osmeridae Salmonidae Scombridae 	Whole

References: Proper name: BP 2023, Ph.Eur. 2023; Common name: BP 2023, Ph.Eur. 2023; Source information: BP 2023, Ph.Eur. 2023, Froese and Pauly 2022.

¹Corresponds to oil from the whole body of one or more of species of the families listed in Table 1 in its natural and/or concentrated triglyceride/triacylglycerol form and/or its concentrated esterified form (BP 2023; Ph.Eur. 2023; Froese and Pauly 2022). The species common names and not the family could be listed on the label.



²For fish oils including species of Gadidae as a source material, the vitamin A and D content should be tested to ensure that the daily maximum amounts meet the Multi-Vitamin/Mineral Supplements monograph for each age group.

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; EMA/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; EMA/CHMP 2006).

Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s)

Products providing 100-5,000 mg eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), per day

- Source of omega-3 fatty acids for the maintenance of good health (EFSA 2012; Simopoulos 2007; Oh 2005; IOM 2002; Simopoulos 1999).
- Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) (EFSA 2012; Simopoulos 2007; Oh 2005; IOM 2002; Simopoulos 1999) for the maintenance of good health

Products providing 150-5,000 mg EPA and DHA including at least 100 mg DHA, per day

- Helps support/maintain cognitive health (EFSA 2012; van de Rest et al. 2008; Freund-Levi et al. 2006; Fontani et al. 2005a,b; Haag 2003; Morris et al. 2003; IOM 2002).
- Helps support/maintain brain function (EFSA 2012; van de Rest et al. 2008; Freund-Levi et al. 2006; Fontani et al. 2005a,b; Haag 2003; Morris et al. 2003; IOM 2002).





Products for children up to 12 years old and providing 200-2,000 mg EPA and DHA including at least 150 mg DHA, per day

Helps support/maintain (healthy) development of brain/(and), eyes/(and) nerves in children up to 12 years of age (Marszalek and Lodish 2005; Haag 2003; IOM 2002; Giedd et al. 1999; Mills 1999).

Products providing 200-5,000 mg EPA and DHA, per day

- Helps support/maintain (normal) heart/cardiovascular health (EFSA 2012; Oh 2005; Wang et al. 2004; Leaf et al. 2003; Kris-Etherton et al. 2002).
- Helps support/maintain (normal) heart/cardiovascular function (EFSA 2012; Oh 2005; Wang et al. 2004; Leaf et al. 2003; Kris-Etherton et al. 2002).

Products providing 1,000-5,000 mg EPA and DHA, per day

- Helps reduce (blood) triglyceride(s)/triacylglycerol(s) (levels) (EFSA 2012; Oh 2005; Balk et al. 2004; Hooper et al. 2004; Nilsen et al. 2001; Sirtori et al. 1998).
- Helps support/maintain normal (blood) triglyceride/triacylglycerol levels (EFSA 2012; Oh 2005; Balk et al. 2004; Hooper et al. 2004; Nilsen et al. 2001; Sirtori et al. 1998).

Products for adults and providing 2,800-5,000 mg EPA and DHA, per day and containing a ratio of EPA:DHA between 0.5:1 and 2:1

In conjunction with conventional therapy, helps reduce the pain of rheumatoid arthritis in adults (EFSA 2012; Volker et al. 2000; Sköldstam et al. 1992).

Products providing 1,500-5,000 mg EPA and DHA including at least 1000 mg EPA, per day

Helps promote healthy mood balance (EFSA 2012; Nemets et al. 2006; Sontrop and Campbell 2006; Fontani et al. 2005a,b; Zanarini and Frankenburg 2003; Peet and Horrobin 2002; Stoll et al. 1999).

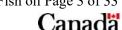
Notes:

- The above uses can be combined on the product label (e.g., Helps reduce triglycerides and maintain cardiovascular health).
- The terms 'Helps' or 'Helps to' can be used interchangeably on the label.

Dose(s)

Subpopulation(s)

As specified below.





Quantity(ies)

Method of preparation: Standardized fixed oil

In addition to the quantity of fish oil, the potency information must be expressed as the quantity (milligrams) and/or percent (%) of EPA and DHA (% w/w) relative to the total quantity of fish oil.

Table 2. Daily dose for eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in fish oil.

Subpopulation(s)		EPA + DHA (mg/day)	
		Minimum ¹	Maximum ²
Children	1-8 years	100	1,500
	9-11 years	100	2,000
Adolescents	12-13 years	100	2,000
	14-17 years	100	2,500
Adults	18 years and older	100	5,000

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

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

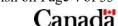
Caution(s) and warning(s)

Pain of rheumatoid arthritis

Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen.

Healthy mood balance

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have psychological disorders such as anxiety or depression.



²Adult maximum dose of EPA + DHA is supported by US FDA 2019 and EFSA 2012. Children and adolescent maximum doses are calculated as a fraction of the adult dose, are relative to body weight and caloric intake.



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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

All products, except those encapsulated

Refrigerate after opening (Wille and Gonus 1989).

All products (information for industry; not for labelling)

To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023).

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 fish oil and omega-3 fatty acids derived from fish 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 fish oil and the omega-3 fatty acids from fish oil (HC 2015). 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 (DL PCBs); and the polychlorinated biphenyls (PCBs) are contaminants in oils from marine sources. Testing



for these contaminants is required. As indicated in the Quality of Natural Health Products Guide, 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. 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. Refer to the Quality of Natural Health Products Guide for more information on the acceptable limits of dioxins and dioxin-like PCBs.

• For fish oils including Gadidae as a source material, the vitamin A and D content should be tested to ensure that their respective daily maximum amounts meet the Multi-Vitamin/Mineral Supplements monograph for each age group.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, Labelling of Natural Health Products for more details.

Product Facts

Medicinal ingredient in each capsule

Fish oil (Atlantic salmon, sardine, tuna - whole)

XX mg

Providing YY mg Eicosapentaenoic acid (EPA); ZZ mg Docosahexaenoic acid (DHA)

Uses

- In conjunction with conventional therapy, helps to reduce the pain of rheumatoid arthritis in adults.
- Helps to promote healthy mood balance.

Warnings

If applicable¹:

Allergens: food allergen, gluten (gluten source), sulphites

Contains aspartame

Ask a health care practitioner before use if you have psychological disorders such as anxiety or depression.

Ask a health care practitioner if symptoms worsen².

Directions

Adults 18 years and older: • Take X capsule(s), X time(s) a day.

Other information

(Add storage information)

Non-medicinal ingredients

List all NMIs

Questions? (Call) 1-XXX-XXXX

¹ This section can be removed from the table if the product contains no allergen or aspartame.

² The qualifier 'For pain of rheumatoid arthritis:' may be added to the label to inform consumers.



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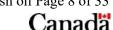
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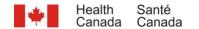
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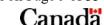
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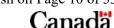
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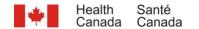
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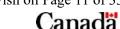
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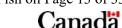
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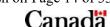
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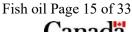
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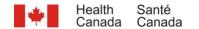
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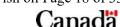
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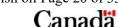
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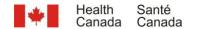
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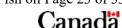
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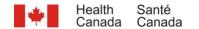
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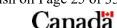
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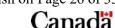
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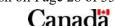
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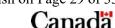
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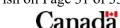
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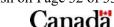
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