Krill Oil

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=krill.oil.huile⟨=eng

Extracted: 2025-08-26T06:34:19.177101

Krill Oil (PDF Version - 99 KB) 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 This monograph only covers naturally-occurring fatty acids in krill oil with EPA, DHA and DPA, including concentrated oils, but excludes krill oils spiked with additional fatty acids. Text in parentheses is additional optional information which can be included on the 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 on the label. Date January 31, 2025 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) Part(s) Krill oil Krill oil Euphausia pacifica Euphausia superba 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 information: 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 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 milligrams or more of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), per day. Potency information for docosapentaenoic acid (DPA) is optional 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 (and DPA 1) (Batetta et al 2009; US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003; IOM 2002). Source of eicosapentaenoic acid (EPA), (and) docosahexaenoic acid (DHA) (and docosapentaenoic acid (DPA) 1) for the maintenance of good health (Batetta et al 2009; US FDA 2008; Bunea et al. 2004; Sampalis et al. 2003; IOM 2002). 1 Note: Docosapentaenoic acid (DPA) can be included in the claim if the potency information for this constituent is also listed. Products providing 200 milligrams or more of EPA and DHA, per day Helps support/maintain (normal) heart/cardiovascular health (EFSA 2012). Helps support/maintain (normal) heart/cardiovascular function (EFSA 2012). Products providing 1,000 milligrams or more of EPA and DHA, per day Helps reduce (blood) triglyceride(s)/triacylglycerol(s) (levels) (EFSA 2012). Helps support/maintain normal (blood) triglyceride/triacylglycerol levels (EFSA 2012). 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) 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). Notes: The potency information for docosapentaenoic acid (DPA) is optional on the PLA form. The following potency information is considered as additional information and can be included on the label: XX% or mg total omega-3 fatty acids. Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 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 2024). 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 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. Example Of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Batetta B, Griinari M, Carta G, Murru E, Ligresti A, Cordeddu L, Giordano E, Sanna F, Bisogno T, Uda S, Collu M, Bruheim I, Di Marzo V, Banni S. Endocannabinoids may mediate the ability of (n-3) fatty acids to reduce ectopic fat and inflammatory mediators in obese Zucker rats. Journal Nutrition 2009;139(8):1495-501. Bunea R, El Farrah K, Deutsch L. Evaluation of the effects of Neptune Krill Oil on the clinical course of hyperlipidemia. Alternative Medicine Review 2004;9(4):420-428 EFSA 2012: European Food Safety Authority. Scientific Opinion: Scientific opinion on the tolerable upper intake level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA). EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 2012;10(7):2815. [Accessed 2023 March 07]. Available from: http://www.efsa.europa.eu/en/efsajournal/doc/2815.pdf HC 2015: Health Canada. Quality of Natural Health Products Guide. Version 3.1 Ottawa (ON): Natural Health Products Directorate, Health Canada. [Accessed 2023 March 07]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/quality-guide.html. HC 2009: Health Canada, It's your health. Food Allergies. Ottawa (ON): Health Canada. [Original: June 2009; Accessed 2024 November 20]. Available from: https://www.hc-sc.gc.ca/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/food-aliment/allerg-eng.pdf IOM 2002: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Food and Nutrition Board, Institute of Medicine. Washington (DC): National Academy Press; 2002. Ph.Eur. 2023: European Pharmacopoeia. 11th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM); 2023. Sampalis F, Bunea R, Pelland MF, Kowalski O, Duguet N, Dupuis S. Evaluation of the effects of Neptune Krill Oil on the management of premenstrual syndrome and dysmenorrhea. Alternative Medicine Review 2003;8(2):171-179. Takaichi S, Matsui K, Nakamura M, Muramatsu M, Hanada S. Fatty acids of astaxanthin esters in krill determined by mild mass spectrometry. Comparative Biochemistry and Physiology - Part B: Biochemistry & Molecular Biology 2003;136(2):317-322. US FDA 2008: GRAS Notice No GRN 000242. Agency letter GRAS Notice No. GRN 000242.. CFSAN/Office of Food Additive Safety. [Accessed 2024 November 20]. Available from: https://waybac k.archive-it.org/7993/20171031031428/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeI nventory/ucm154374.htm USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2024. Wille HJ, Gonus P. Preparation of Fish Oil for Dietary Applications. In: Galli C, Simopolous AP, editors. Dietary ω3 and ω6 Fatty Acids. Biological Effects and Nutritional Essentiality. New York (NY): Plenum Press; 1989. References Reviewed Augusti PR, Conterato GM, Somacal S, Sobieski R, Spohr PR, Torres JV, Charão MF, Moro AM, Rocha MP, Garcia SC, Emanuelli T. Effect of astaxanthin on kidney function impairment and oxidative stress induced by mercuric chloride in rats. Food and Chemical Toxicology 2008;46(1):212-219. Calder P C. Dietary modification of inflammation with lipids. Proceedings of the Nutrition Society 2002;61:345-358. Commission of the European Communities. Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down the methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs. Official Journal of the European Union L 364/32 20.12.2006. [Accessed 2024 November 20]. Available from: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0032:0043:EN:PDF Commission of the European Communities. Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. Official Journal of the European Union L 364/5 20.12.2006. [Accessed 2024 November 20]. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0005:0024:EN:PDF Grimm H, Mayer K, Mayser P, Eigenbrodt E. Regulatory potential of n-3 fatty acids in immunological and inflammatory processes. British Journal of Nutrition 2002;87(suppl):S59S67. Harbige LS. Fatty acids, the immune response, and autoimmunity: a question of n-6 essentiality and the balance between n-6 and n-3. Lipids 2003;38:323-341. Higuera-Ciapara I, Félix-Valenzuela L, Goycoolea FM. Astaxanthin: a review of its chemistry and applications. Critical Reviews in Food Science and Nutrition 2006;46(2):185-96. Naguib YM. Antioxidant activities of astaxanthin and related

carotenoids. Journal of Agriculture and Food Chemistry 2000;48(4):1150-1154. Simopoulos AP. Omega-3 fatty acids in health and disease and in growth and development. American Journal of Clinical Nutrition 1991;54:438-463. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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

DOSAGE FORM(S)

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.

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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 2024).

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 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.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Krill oil	Krill oil	Euphausia pacificaEuphausia superba	Whole