

Fixed Oil Products - Oral

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Fixed Oil Products - Oral Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 409 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA s) for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients. Notes This monograph only covers naturally-occurring fatty acids in each fixed oil, including concentrated oils, but excludes fixed oils spiked with additional fatty acids. Essential/volatile oil preparations (e.g. those prepared by distillation) are not within the scope of this monograph. Hydrogenated oils and partially hydrogenated oils are not within the scope of this monograph. This monograph may be used to support single ingredient or multi-ingredient products containing any medicinal ingredient from Table 1. 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 or statements are synonymous. Either term or statement may be selected by the applicant on the label. Date March 28, 2025 Proper name(s), Common name(s), and Source information Table 1. Proper name(s), Common name(s) and Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Borago officinalis Borage oil Borage seed oil Borago officinalis Seed Camelina sativa False flax oil Camelina sativa Seed Cannabis sativa Hemp seed oil Cannabis sativa Non-viable Seed Canola Oil Canola oil Colza oil Rapeseed oil Brassica napus Brassica juncea Brassica rapa Seed Carthamus tinctorius Safflower oil Carthamus tinctorius Seed Cocos nucifera Coconut oil Cocos nucifera Seed endosperm Cod liver oil Cod liver oil Lecoris aselli oleum Gadidae 1 Liver Cucurbita pepo Pumpkin seed oil Cucurbita pepo Seed Fish oil 2 Fish oil Ammodytidae Carangidae Clupeidae Engraulidae Gadidae 3 Osmeridae Salmonidae Scombridae Whole Helianthus annuus Sunflower oil Helianthus annuus Seed Hippophae rhamnoides Sea buckthorn fruit oil Hippophae rhamnoides Fruit Sea buckthorn seed oil Hippophae rhamnoides Seed Krill oil Krill oil Euphasia pacifica Euphausia superba Whole Linum usitatissimum Flax oil Flaxseed oil Linseed oil Linum usitatissimum Seed Oenothera biennis Evening primrose oil Primrose oil Oenothera biennis Seed Olea europaea Olive oil Olea europaea Fruit Prunus dulcis Almond oil Sweet almond oil Prunus dulcis Seed Ribes nigrum Blackcurrant seed oil Ribes nigrum Seed Salvia hispanica Chia seed oil Salvia hispanica Seed Schizochytrium spp Schizochytrium oil Schizochytrium spp. Whole Seal oil Seal oil Cystophora cristata Erignathus barbatus Halichoerus grypus Pagophilus groenlandicus Phoca vitulina Pusa hispida Blubber Squid oil Squid oil Todarodes pacificus Docidicus gigas Illex argentinus Illex illecebrosus Whole Triticum aestivum Wheat germ oil Triticum aestivum Seed germ Vitis vinifera Grape seed oil Vitis vinifera Seed References: Proper names: NHPID 2025; Common names: NHPID 2025; Source information: FCC 2023; ITIS 2023; USP-NF 2023; Ph.Eur. 2023; Linnamaa et al. 2010; Yurko-Mauro et al. 2010; Dubois et al. 2007; Callaway et al. 2005; Hoffmann 2003; Yang et al. 1999. 1 Cod liver oil: The species common names and not the family could be listed on the label. 2 Fish oil: Corresponds to oil from the whole body of one or more 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. 3 Fish oil: For 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 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) and Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Refer to Tables 2 and 3. Table 2. Uses or purposes, associated daily dose and potency constituents (LA - Linoleic acid; ALA - Alpha-linolenic acid; EPA - Eicosapentaenoic acid; DHA - Docosahexaenoic acid; DPA - Docosapentaenoic acid; GLA-Gamma-linolenic acid; OA - Oleic acid) Medicinal ingredient Methods of preparation Uses or Purposes Daily Dose 1 Potency Constituents Borage oil Non-standardized fixed oil As per Borage oil monograph As per Borage oil monograph N/A Standardized fixed oil As per Table 3 Oil: up to 5 g and LA, ALA, GLA and/or OA as per Table 3* LA, ALA, GLA, OA Hemp seed oil Non-standardized fixed oil N/A Oil: up to 15 g

N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA, ALA, GLA and/or OA as per Table 3* LA, ALA, GLA, OA Canola oil Non-standardized fixed oil N/A Oil: up to 15 g N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3*. LA, ALA, OA False flax Oil Non-standardized fixed oil N/A Oil: up to 15 g N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3*. LA, ALA, OA Safflower oil Non-standardized fixed oil N/A Oil: up to 15 g N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3*. LA, ALA, OA Coconut oil Non-standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals Oil: up to 15 g N/A Standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals and/or As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3* LA, ALA, OA Cod liver oil Standardized fixed oil As per Cod liver oil monograph As per Cod liver oil monograph EPA, DHA, Vitamin A, Vitamin D As per Table 3 Oil: up to 4 g and Minimum amounts of EPA and DHA as per Table 3* and Maximum amounts of EPA, DHA, Vitamin A and Vitamin D as per the Cod liver oil monograph Pumpkin seed oil Non-standardized fixed oil N/A Oil: up to 15 g N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA and/or OA as per Table 3* LA, OA Fish oil Standardized fixed oil As per Fish oil monograph As per Fish oil monograph EPA, DHA As per Table 3 Oil: up to 10 g and EPA and DHA as per Table 3* Sunflower oil Non-standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals Oil: up to 15 g N/A Standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals and/or As per Table 3 Oil: up to 15 g and LA and/or OA as per Table 3* LA, OA Sea buckthorn seed oil Non-standardized fixed oil N/A Oil: up to 5 g N/A Standardized fixed oil As per Table 3 Oil: up to 5 g and LA, ALA and/or OA as per Table 3*. LA, ALA, OA Sea buckthorn fruit oil Non-standardized fixed oil N/A Oil: up to 5 g N/A Standardized fixed oil As per Table 3 Oil: up to 5 g and LA, ALA and/or OA as per Table 3*. LA, ALA, OA Krill oil Standardized fixed oil As per Krill oil monograph As per Krill oil monograph EPA, DHA, DPA As per Table 3 Oil: up to 4.1 g and EPA and DHA as per Table 3* Flaxseed oil Non-Standardized fixed oil As per Flaxseed oil monograph As per Flaxseed oil monograph N/A Standardized fixed oil As per Table 3 Oil: up to 32 g and LA, ALA and/or OA as per Table 3* LA, ALA, OA Evening primrose oil Non-standardized fixed oil As per Evening primrose oil monograph As per Evening primrose oil monograph N/A Standardized fixed oil As per Table 3 Oil: up to 6 g and LA, ALA, GLA and/or OA as per Table 3* LA, ALA, GLA, OA Olive oil Non-standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals Oil: up to 15 g N/A Standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals and/or As per Table 3 Oil: up to 15 g and LA and/or OA as per Table 3* LA, OA Almond oil Non-standardized fixed oil N/A Oil: up to 15 g N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3* LA, ALA, OA Blackcurrant seed oil Non-standardized fixed oil N/A Oil: up to 10.5 g N/A Standardized fixed oil As per Table 3 Oil: up to 10.5 g and LA, ALA, GLA and/or OA as per Table 3* LA, ALA, GLA, OA Chia seed oil Non-standardized fixed oil N/A Oil: up to 4.5 g N/A Standardized fixed oil As per Table 3 Oil: up to 4.5 g and LA, ALA and/or OA as per Table 3* LA, ALA, OA Schizochytrium oil Standardized fixed oil Helps support cognitive/brain health/function DHA: 200-2,000 mg EPA, DHA As per Table 3 (except the use for cognitive health and/or brain function) Oil: up to 5 g and EPA and/or DHA as per Table 3* Seal oil Standardized fixed oil As per Seal oil monograph As per Seal oil monograph EPA, DHA, DPA As per Table 3 Oil: up to 10 g and EPA and DHA (and DPA) as per Table 3* Squid oil Non-standardized fixed oil N/A Oil: up to 5 g N/A Standardized fixed oil As per Table 3 Oil: up to 5 g and EPA and DHA as per Table 3* EPA, DHA Wheat germ oil Non-standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals Oil: up to 15 g N/A Standardized fixed oil Source of antioxidants/Provides antioxidants Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals and/or As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3* LA, ALA, OA Grape seed oil Non-standardized fixed oil N/A Oil: up to 15 g N/A Standardized fixed oil As per Table 3 Oil: up to 15 g and LA, ALA and/or OA as per Table 3* LA, ALA, OA References: NNHPD 2023; Zielinska et al. 2017; Quinn et al. 2010; Yang et al. 1999; Leventhal et al. 1994. 1 The amount of fixed oils can also be represented in volumetric amount (i.e., mL) based on the density information listed in Appendix 1. *The total amount of a specific fatty acid (e.g., LA) in the product should meet the minimum dose as per Table 3 to

support a claim from this table. It is not required that each oil meets the minimum amount of specific fatty acids if the total amount of a fatty acid in the finished product meets it. Table 3. Uses or Purposes based on potency constituents - fatty acids

Potency constituents:	Fatty acids	1 Uses or Purposes	Minimum Daily Doses	2 LA
Source of linoleic acid (LA) for the maintenance of good health	Source of omega-6 fatty acid for the maintenance of good health	Source of an essential fatty acid for the maintenance of good health	850 mg	ALA
Source of alpha-linolenic acid (ALA) for the maintenance of good health	Source of omega-3 fatty acid for the maintenance of good health	Source of an essential fatty acid for the maintenance of good health	80 mg	LA + ALA
Source of essential fatty acids for the maintenance of good health	850 mg	LA And 80 mg	ALA	EPA + DHA (+ DPA 3)
Source of omega-3 fatty acids for the maintenance of good health	Source of essential fatty acids for the maintenance of good health	Source of eicosapentaenoic acid (EPA), (and) docosahexaenoic acid (DHA) (and docosapentaenoic acid (DPA) 3) for the maintenance of good health	EPA + DPA: 100 mg	Helps support/maintain cognitive health
Source of eicosapentaenoic acid (EPA), (and) docosahexaenoic acid (DHA) (and docosapentaenoic acid (DPA) 3) for the maintenance of good health	EPA + DPA: 100 mg	Helps support/maintain brain function	150 mg	EPA + DHA including at least 100 mg
Helps support/maintain (normal) heart/ cardiovascular health	Helps support/maintain (normal) heart/ cardiovascular function	EPA + DHA: 200 mg	Helps support/maintain normal (blood) triglyceride/triacylglycerol levels	Helps reduce (blood) triglyceride(s)/ triacylglycerol(s) (levels)
EPA + DHA: 1000 mg	EPA	Source of eicosapentaenoic acid (EPA) for the maintenance of good health	Source of omega-3 fatty acid for the maintenance of good health	Source of an essential fatty acid for the maintenance of good health
100 mg	DHA	Source of docosahexaenoic acid (DHA) for the maintenance of good health	Source of omega-3 fatty acid for the maintenance of good health	Source of an essential fatty acid for the maintenance of good health
100 mg	GLA	Source of gamma-linoleic acid (GLA) for the maintenance of good health	Source of omega-6 fatty acid for the maintenance of good health	Source of an essential fatty acid for the maintenance of good health
100 mg	OA	Source of oleic acid (OA) 100 mg	1	For products making claims from this table, the potencies must be indicated for the relevant fatty acid constituents.

2 References: NNHPD 2023; EFSA 2010a; EFSA 2010b; EFSA 2009; Simopolous 2007; IOM 2006; IOM 2002; Simopolous 1999. 3 Docosapentaenoic acid (DPA) can be included in the claim if the potency information for this constituent is also listed. 4 For Schizochytrium oil, the specific quantity listed in Table 2 for the cognitive/brain health/function applies (i.e., DHA: 200 - 2000 mg per day). 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. The following potency information is considered as additional information and can be included on the label: XX% or mg total omega-3 (or omega-6) fatty acids. Direction(s) for use No statement required. Combination rules and restrictions A use or purpose statement is only acceptable if at least one medicinal ingredient/potency constituent associated with that statement is present at a dose at or above the minimum daily dose listed in Tables 2 and 3. Medicinal ingredients which do not meet the minimum daily dose for a use or purpose statement will be considered as acceptable complementary medicinal ingredients in product formulations. All medicinal ingredients included in this monograph may be combined with the following restrictions: The combined maximum daily dose of oils in a product must not exceed 15.0 g per day (NNHPD 2023). Maximum daily doses for individual medicinal ingredient as per Table 2 apply. The combined maximum daily dose of EPA+DHA in a single product must not exceed 5,000 mg for 18 years and older per day (US FDA 2019; EFSA 2012). Duration(s) of Use No statement required. Risk Information Caution(s) and warnings(s) Products containing Hemp seed oil, Sea buckthorn seed oil, Krill oil, Blackcurrant seed oil and/or Squid oil Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Products containing fish oil 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. Contraindication(s) No statements required. Known adverse reaction(s) Products containing Krill oil and/or Squid oil Stop use if hypersensitivity/allergy occurs (HC 2017). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations. Products containing Schizochytrium oil, False flax oil, Hemp seed oil, Cod liver oil, Fish oil, Sea buckthorn seed oil, Krill oil, Flaxseed oil, Black current seed oil, Chia seed oil, Seal oil and Squid Oil 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 ingredients must comply with the requirements outlined in the NHPID. Cod liver oil, Fish oil, Krill oil,

Seal oil and Squid oil are considered marine oils and therefore the requirements for the contaminants in marine oils of the NNHPD Quality of Natural Health Products Guide applies to products containing these ingredients apply. The requirements for the oxidative stability in oils of the NNHPD Quality of Natural Health Products Guide applies to all products containing any medicinal ingredient on this monograph. For all products indicating one or more of the potencies listed in the dose section, an assay must be performed in order to confirm the potency(ies). Fish oil from Gadidae species 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. Hemp seed oil This monograph is for Cannabis sativa seed oil from hemp only. Hemp is defined in the Industrial Hemp regulations (IHR) as “ a cannabis plant — or any part of that plant — in which the concentration of THC is 0.3% w/w or less in the flowering heads and leaves ”. Approved hemp cultivars are set out in the List of Approved Cultivars, published by the Government of Canada on its website, as amended from time to time. Additional cultivars may be permitted such as those on the Association of Official Seed Certifying Agencies (AOSCA) list which also meet the definition of Hemp set out in the IHR. Products containing hemp seed oil must not contain more than 10 parts per million delta-9-Tetrahydrocannabinol (THC), or phytocannabinoids that have been isolated or concentrated, or synthetic duplicates of phytocannabinoids. The determination of the THC concentration must take into account the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) to THC. Example of Product Facts Consult the Guidance Document, Labelling of Natural Health Products for more details.

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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>. Firestone, D, editor. Physical and chemical characteristics of oils, fats, and waxes, 3rd edition. Urbana (IL): American Oil Chemists' Society; 2013. Fitzpatrick KC. 2005. Invitational Consultation on Fatty Acids. Winnipeg (MB): Nutritech Consulting. Food Chemicals Codex. Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2023. HC 2017: Health Canada. Crustaceans and Molluscs. Priority food allergens. [Accessed 2023 March 07]. Available from: <https://www.canada.ca/content/dam/hc-sc/documents/services/food-nutrition/reports-publications/food-safety/2017-crustaceans-crustaceans-eng.pdf> Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. 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acid and uremic skin symptoms in hemodialysis patients. *Nephron* 1999;81(2):151-159. Yzebe D, Lievre M. Fish oils in the care of coronary heart disease patients: a meta-analysis of randomized controlled trials. *Fundamental & Clinical Pharmacology* 2004;18(5):581-592. Appendix I Density of the fixed oils Fixed oils Parts Density Borage oil Seed 0.908 - 0.925 g/mL False flax oil Seed 0.918 - 0.927 g/mL Hemp Seed Oil Non-viable seed 0.920 - 0.930 g/mL Canola Oil Seed 0.917 - 0.923 g/mL* Safflower Oil Seed 0.918 - 0.937 g/mL Coconut Oil Seed endosperm 0.913 - 0.919 g/mL Cod liver oil Liver 0.921 - 0.927 g/mL Pumpkin seed oil Seed 0.901 - 0.924 g/mL Fish oil Whole 0.929 - 0.931 g/mL Sunflower oil Seed 0.919 - 0.920 g/mL Sea buckthorn fruit oil Fruit 0.913 - 0.919 g/mL Sea buckthorn seed oil Seed 0.913 - 0.919 g/mL Krill oil Whole 0.919 - 0.925 g/mL* Flaxseed oil Seed 0.928 - 0.935 g/mL Evening Primrose Oil Seed 0.918 - 0.930 g/mL Olive oil Fruit 0.908 - 0.914 g/mL Sweet Almond Oil Seed 0.913 - 0.919 g/mL* Blackcurrant seed oil Seed 0.919 - 0.926 g/mL Chia seed oil Seed 0.922 - 0.927 g/mL Schizochytrium Oil (algal oil) Whole 0.944 - 0.950 g/mL Seal oil Blubber 0.921 - 0.927 g/mL* Squid oil Whole 0.953 - 0.959 g/mL* Wheat germ oil Seed germ 0.922 - 0.937 g/mL Grape Seed oil Seed 0.921 - 0.924 g/mL *When only a single value was found in the evidence, a variation of +/- 0.003 g/mL was applied to allow for potential variability. At least one of the following references was used to support density ranges: Moovendhan 2023; Turck et al. 2021; Purnamayati et al. 2019; Uzunova et al. 2019; Delgado-et al. 2018; Petcu et al. 2016; Lee et al. 2014; Edwin et al. 2013; Firestone 2013; Manisha and Sharma 2011; Zhang et al. 2011; Alamu et al. 2010; Budavari 1996; Subrahmanyam et al. 1994; Kyte R.M. 1956. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Notes This monograph only covers naturally-occurring fatty acids in each fixed oil, including concentrated oils, but excludes fixed oils spiked with additional fatty acids. Essential/volatile oil preparations (e.g. those prepared by distillation) are not within the scope of this monograph. Hydrogenated oils and partially hydrogenated oils are not within the scope of this monograph. This monograph may be used to support single ingredient or multi-ingredient products containing any medicinal ingredient from Table 1. 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 or statements are synonymous. Either term or statement may be selected by the applicant on the label. Date March 28, 2025 Proper name(s), Common name(s), and Source information Table 1. Proper name(s), Common name(s) and Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Borago officinalis Borage oil Borage seed oil Borago officinalis Seed Camelina sativa False flax oil Camelina sativa Seed Cannabis sativa Hemp seed oil Cannabis sativa Non-viable Seed Canola Oil Canola oil Colza oil Rapeseed oil Brassica napus Brassica juncea Brassica rapa Seed Carthamus tinctorius Safflower oil Carthamus tinctorius Seed Cocos nucifera Coconut oil Cocos nucifera Seed endosperm Cod liver oil Cod liver oil Lecoris aselli oleum Gadidae 1 Liver Cucurbita pepo Pumpkin seed oil Cucurbita pepo Seed Fish oil 2 Fish oil Ammodytidae Carangidae Clupeidae Engraulidae Gadidae 3 Osmeridae Salmonidae Scombridae Whole Helianthus annuus Sunflower oil Helianthus annuus Seed Hippophae rhamnoides Sea buckthorn fruit oil Hippophae rhamnoides Fruit Sea buckthorn seed oil Hippophae rhamnoides Seed Krill oil Krill oil Euphasia pacifica Euphausia superba Whole Linum usitatissimum Flax oil Flaxseed oil Linseed oil Linum usitatissimum Seed Oenothera biennis Evening primrose oil Primrose oil Oenothera biennis Seed Olea europaea Olive oil Olea europaea Fruit Prunus dulcis Almond oil Sweet almond oil Prunus dulcis Seed Ribes nigrum Blackcurrant seed oil Ribes nigrum Seed Salvia hispanica Chia seed oil Salvia hispanica Seed Schizochytrium spp Schizochytrium oil Schizochytrium spp. Whole Seal oil Seal oil Cystophora cristata Erignathus barbatus Halichoerus grypus Pagophilus groenlandicus Phoca vitulina Pusa hispida Blubber Squid oil Squid oil Todarodes pacificus Docidicus gigas Illex argentinus Illex illecebrosus Whole Triticum aestivum Wheat germ oil Triticum aestivum Seed germ Vitis vinifera Grape seed oil Vitis vinifera Seed

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.

USE(S) OR PURPOSE(S)

Medicinal ingredient	Methods of preparation	Uses or Purposes	Daily Dose	Potency	Constituents
Borage oil	Non-standardized fixed oil	As per Borage oil monograph	As per Borage oil monograph	N/A	Standardized fixed oil
As per Table 3	Oil: up to 5 g and LA, ALA, GLA and/or OA as per Table 3*	LA, ALA, GLA, OA	Hemp seed oil	Non-standardized fixed oil	N/A
Oil: up to 15 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 15 g and LA, ALA, GLA and/or OA as per Table 3*	LA, ALA, GLA, OA	Canola oil
Non-standardized fixed oil	N/A	Oil: up to 15 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*
LA, ALA, OA	False flax Oil	Non-standardized fixed oil	N/A	Standardized fixed oil	As per Table 3
Oil: up to 15 g and LA, ALA and/or OA as per Table 3*	LA, ALA, OA	Safflower oil	Non-standardized fixed oil	N/A	Standardized fixed oil
Oil: up to 15 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*	LA, ALA, OA	Coconut oil
Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals	Oil: up to 15 gN/A	Standardized fixed oil	Source of antioxidants/Provides antioxidants
Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals	and/or	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*	LA, ALA, OA
Cod liver oil	Standardized fixed oil	As per Cod liver oil monograph	EPA, DHA, Vitamin A, Vitamin D	As per Table 3	Oil: up to 4 g and Minimum amounts of EPA and DHA as per Table 3* and Maximum amounts of EPA, DHA, Vitamin A and Vitamin D as per the Cod liver oil monograph
Pumpkin seed oil	Non-standardized fixed oil	N/A	Standardized fixed oil	As per Table 3	Oil: up to 15 g and LA and/or OA as per Table 3*
LA, OA	Fish oil	Standardized fixed oil	As per Fish oil monograph	EPA, DHA	As per Table 3
Oil: up to 10 g and EPA and DHA as per Table 3*	Sunflower oil	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals	Oil: up to 15 gN/A
Standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals	and/or	As per Table 3	Oil: up to 15 g and LA and/or OA as per Table 3*
LA, OA	Sea buckthorn seed oil	Non-standardized fixed oil	N/A	Standardized fixed oil	As per Table 3
Oil: up to 5 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 5 g and LA, ALA and/or OA as per Table 3*	LA, ALA, OA	Sea buckthorn fruit oil
Non-standardized fixed oil	N/A	Oil: up to 5 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 5 g and LA, ALA and/or OA as per Table 3*
LA, ALA, OA	Krill oil	Standardized fixed oil	As per Krill oil monograph	EPA, DHA, DPA	As per Table 3
Oil: up to 4.1 g and EPA and DHA as per Table 3*	Flaxseed oil	Non-Standardized fixed oil	As per Flaxseed oil monograph	N/A	Standardized fixed oil
As per Table 3	Oil: up to 32 g and LA, ALA and/or OA as per Table 3*	LA, ALA, OA	Evening primrose oil	Non-standardized fixed oil	As per Evening primrose oil monograph
As per Evening primrose oil monograph	N/A	Standardized fixed oil	As per Table 3	Oil: up to 6 g and LA, ALA, GLA and/or OA as per Table 3*	LA, ALA, GLA, OA
Olive oil	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals	Oil: up to 15 gN/A	Standardized fixed oil
Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals	and/or	As per Table 3	Oil: up to 15 g and LA and/or OA as per Table 3*	LA, OA
Almond oil	Non-standardized fixed oil	N/A	Standardized fixed oil	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*
LA, ALA, OA	Blackcurrant seed oil	Non-standardized fixed oil	N/A	Standardized fixed oil	As per Table 3
Oil: up to 10.5 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 10.5 g and LA, ALA, GLA and/or OA as per Table 3*	LA, ALA, GLA, OA	Chia seed oil
Non-standardized fixed oil	N/A	Oil: up to 4.5 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 4.5 g and LA, ALA and/or OA as per Table 3*
LA, ALA, OA	Schizochytrium oil	Standardized fixed oil	Helps support cognitive/brain health/function	DHA: 200-2,000 mg	EPA, DHA
As per Table 3 (except the use for cognitive health and/or brain function)	Oil: up to 5 g and EPA and/or DHA as per Table 3*	Seal oil	Standardized fixed oil	As per Seal oil monograph	EPA, DHA, DPA
As per Seal oil monograph	As per Table 3	Oil: up to 10 g and EPA and DHA (and DPA) as per Table 3*	Squid oil	Non-standardized fixed oil	N/A
Standardized fixed oil	As per Table 3	Oil: up to 5 gN/A	Standardized fixed oil	As per Table 3	Oil: up to 5 g and EPA and DHA as per Table 3*
EPA, DHA	Wheat germ oil	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the	

oxidative damage caused by/cell damage caused by) free radicalsOil: up to 15 gN/AStandardized fixed oilSource of antioxidants/Provides antioxidantsSource of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals and/orAs per Table 3Oil: up to 15 g and LA, ALA and/or OA as per Table 3*LA, ALA, OAGrape seed oilNon-standardized fixed oilN/AOil: up to 15 gN/AStandardized fixed oilAs per Table 3Oil: up to 15 g and LA, ALA and/or OA as per Table 3*LA, ALA, OA

RISK INFORMATION

Caution(s) and warnings(s) Products containing Hemp seed oil, Sea buckthorn seed oil, Krill oil, Blackcurrant seed oil and/or Squid oil Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Products containing fish oil 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. Contraindication(s) No statements required. Known adverse reaction(s) Products containing Krill oil and/or Squid oil Stop use if hypersensitivity/allergy occurs (HC 2017).

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database. Storage conditions Must be established in accordance with the requirements described in theNatural Health Products Regulations. Products containing Schizochytrium oil, False flax oil, Hemp seed oil, Cod liver oil, Fish oil, Sea buckthorn seed oil, Krill oil, Flaxseed oil, Black current seed oil, Chia seed oil, Seal oil and Squid Oil 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).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations. Products containing Schizochytrium oil, False flax oil, Hemp seed oil, Cod liver oil, Fish oil, Sea buckthorn seed oil, Krill oil, Flaxseed oil, Black current seed oil, Chia seed oil, Seal oil and Squid Oil 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 ingredients must comply with the requirements outlined in the NHPID.Cod liver oil, Fish oil, Krill oil, Seal oil and Squid oil are considered marine oils and therefore the requirements for the contaminants in marine oils of the NNHPD Quality of Natural Health Products Guide applies to products containing these ingredients apply.The requirements for the oxidative stability in oils of the NNHPD Quality of Natural Health Products Guide applies to all products containing any medicinal ingredient on this monograph.For all products indicating one or more of the potencies listed in the dose section, an assay must be

performed in order to confirm the potency(ies). Fish oil from Gadidae species 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. Hemp seed oil This monograph is for Cannabis sativa seed oil from hemp only. Hemp is defined in the Industrial Hemp regulations (IHR) as “a cannabis plant — or any part of that plant — in which the concentration of THC is 0.3% w/w or less in the flowering heads and leaves”. Approved hemp cultivars are set out in the List of Approved Cultivars, published by the Government of Canada on its website, as amended from time to time. Additional cultivars may be permitted such as those on the Association of Official Seed Certifying Agencies (AOSCA) list which also meet the definition of Hemp set out in the IHR. Products containing hemp seed oil must not contain more than 10 parts per million delta-9-Tetrahydrocannabinol (THC), or phytocannabinoids that have been isolated or concentrated, or synthetic duplicates of phytocannabinoids. The determination of the THC concentration must take into account the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) to THC. Example of Product Facts

REFERENCES

1Cod liver oil: The species common names and not the family could be listed on the label. 2Fish oil: Corresponds to oil from the whole body of one or more 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. 3Fish oil: For 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

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Borago officinalis	Borage oil Borage seed oil	Borago officinalis	Seed
Camelina sativa	False flax oil	Camelina sativa	Seed
Cannabis sativa	Hemp seed oil	Cannabis sativa	Non-viable Seed
Canola Oil	Canola oil Colza oil Rapeseed oil	Brassica napus Brassica juncea Brassica rapa	Seed
Carthamus tinctorius	Safflower oil	Carthamus tinctorius	Seed
Cocos nucifera	Coconut oil	Cocos nucifera	Seed endosperm
Cod liver oil	Cod liver oil Lecoris aselli oleum	Gadidae ¹	Liver
Cucurbita pepo	Pumpkin seed oil	Cucurbita pepo	Seed
Fish oil ²	Fish oil	Ammodontidae Carangidae Clupeidae Engraulidae Gobiidae Macrouridae Mugilidae Osteichthys Pleuronectidae Scombridae Stomiidae Tetraodontidae Xiphiidae	Whole
Helianthus annuus	Sunflower oil	Helianthus annuus	Seed
Hippophae rhamnoides	Sea buckthorn fruit oil	Hippophae rhamnoides	Fruit
Sea buckthorn seed oil	Hippophae rhamnoides	Seed	
Krill oil	Krill oil	Euphausia pacifica Euphausia superba	Whole
Linum usitatissimum	Flax oil Flaxseed oil Linseed oil	Linum usitatissimum	Seed
Oenothera biennis	Evening primrose oil Primrose oil	Oenothera biennis	Seed
Olea europaea	Olive oil	Olea europaea	Fruit
Prunus dulcis	Almond oil Sweet almond oil	Prunus dulcis	Seed

Ribes nigrum	Blackcurrant seed oil	Ribes nigrum	Seed
Salvia hispanica	Chia seed oil	Salvia hispanica	Seed
Schizochytrium spp	Schizochytrium oil	Schizochytrium spp.	Whole
Seal oil	Seal oil	Cystophora cristataErignathus barbatulusHalichthys reticulataHeterostichus rostratusPagophilus	Whole
Squid oil	Squid oil	Todarodes pacificusDocidicus gigasIllex argenteusIllex illecebrosus	Whole
Triticum aestivum	Wheat germ oil	Triticum aestivum	Seed germ
Vitis vinifera	Grape seed oil	Vitis vinifera	Seed

	Methods of preparation	Uses or Purposes	Daily Dose ¹	Potency
	Non-standardized fixed oil	As per Borage oil monograph	As per Borage oil monograph	N/A
	As per Table 3	Oil: up to 5 g and LA, ALA, GLA and/or OA as per Table 3*	As per Table 3*	
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA, ALA, GLA and/or OA as per Table 3*	As per Table 3*	
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*	As per Table 3*, OA	
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*	As per Table 3*, OA	
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3*	As per Table 3*, OA	
	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	the help
	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	the help
	Standardized fixed oil	As per Cod liver oil monograph	As per Cod liver oil monograph	EPA, D
	Oil: up to 4 g and Minimum amounts of EPA and DHA as per Table 3* and Maximum amounts of EPA, DHA, Vitamin A and Vitamin D	As per the		
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA and/or OA as per Table 3*	As per Table 3*, OA	
	Standardized fixed oil	As per Fish oil monograph	As per Fish oil monograph	EPA, D
	Oil: up to 10 g and EPA and DHA as per Table 3*			
	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	the help
	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	the help
	Non-standardized fixed oil	N/A	Oil: up to 5 g	N/A
	As per Table 3	Oil: up to 5 g and LA, ALA and/or OA as per Table 3*	As per Table 3*, OA	
	Non-standardized fixed oil	N/A	Oil: up to 5 g	N/A
	As per Table 3	Oil: up to 5 g and LA, ALA and/or OA as per Table 3*	As per Table 3*, OA	
	Standardized fixed oil	As per Krill oil monograph	As per Krill oil monograph	EPA, D
	Oil: up to 4.1 g and EPA and DHA as per Table 3*			
	Non-Standardized fixed oil	As per Flaxseed oil monograph	As per Flaxseed oil monograph	N/A
	As per Table 3	Oil: up to 32 g and LA, ALA and/or OA as per Table 3*	As per Table 3*, OA	
	Non-standardized fixed oil	As per Evening primrose oil monograph	As per Evening primrose oil monograph	N/A

	As per Table 3	Oil: up to 6 g and LA, ALA, GLA and/or OA as per Table 3	LA, ALA, GLA, OA	
	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	N/A
	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	N/A
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3	LA, ALA, OA	
	Non-standardized fixed oil	N/A	Oil: up to 10.5 g	N/A
	As per Table 3	Oil: up to 10.5 g and LA, ALA, GLA and/or OA as per Table 3	LA, ALA, GLA, OA	
	Non-standardized fixed oil	N/A	Oil: up to 4.5 g	N/A
	As per Table 3	Oil: up to 4.5 g and LA, ALA and/or OA as per Table 3	LA, ALA, OA	
	Standardized fixed oil	Helps support cognitive/brain health/function	DHA: 200-2,000 mg	EPA, DHA
cognitive health and brain function	Oil: up to 5 g and EPA and DHA as per Table 3*			
	Standardized fixed oil	As per Seal oil monograph	As per Seal oil monograph	EPA, DHA
	Oil: up to 10 g and EPA and DHA (and DPA) as per Table 3*			
	Non-standardized fixed oil	N/A	Oil: up to 5 g	N/A
	As per Table 3	Oil: up to 5 g and EPA and DHA as per Table 3	EPA, DHA	
	Non-standardized fixed oil	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	N/A
	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	Source of antioxidants/Provides antioxidants	N/A
	Non-standardized fixed oil	N/A	Oil: up to 15 g	N/A
	As per Table 3	Oil: up to 15 g and LA, ALA and/or OA as per Table 3	LA, ALA, OA	

Potency constituents: Fatty acids ¹	Uses or Purposes	Minimum Daily Doses ²
LA	Source of linoleic acid (LA) for the maintenance of good health	850 mg
ALA	Source of alpha-linolenic acid (ALA) for the maintenance of good health	80 mg
LA + ALA	Source of essential fatty acids for the maintenance of good health	850 mg LA and 80 mg ALA
EPA + DHA (+ DPA ³)	Source of omega-3 fatty acids for the maintenance of good health	EPA + DHA 100 mg
Helps support/maintain cognitive health	Helps support/maintain brain function	At least 100 mg DHA ⁴
Helps support/maintain (normal) heart/ cardiovascular function	Helps support/maintain (normal) heart/ cardiovascular function	EPA + DHA 200 mg
Helps support/maintain normal (blood) triglyceride(s) levels	Helps reduce (blood) triglyceride(s)/ triacylglycerol(s) (levels)	EPA + DHA 100 mg
EPA	Source of eicosapentaenoic acid (EPA) for the maintenance of good health	100 mg
DHA	Source of docosahexaenoic acid (DHA) for the maintenance of good health	100 mg
Helps support/maintain eye health/function	Helps support/maintain visual health/function	
DPA	Source of docosapentaenoic acid (DPA) for the maintenance of good health	100 mg
GLA	Source of gamma-linoleic acid (GLA) for the maintenance of good health	100 mg
OA	Source of oleic acid (OA)	100 mg

Fixed oils	Parts	Density
Borage oil	Seed	0.908 - 0.925 g/mL

False flax oil	Seed	0.918 - 0.927 g/mL
Hemp Seed Oil	Non-viable seed	0.920 - 0.930 g/mL
Canola Oil	Seed	0.917 - 0.923 g/mL*
Safflower Oil	Seed	0.918 - 0.937 g/mL
Coconut Oil	Seed endosperm	0.913 - 0.919 g/mL
Cod liver oil	Liver	0.921 - 0.927 g/mL
Pumpkin seed oil	Seed	0.901 - 0.924 g/mL
Fish oil	Whole	0.929 - 0.931 g/mL
Sunflower oil	Seed	0.919 - 0.920 g/mL
Sea buckthorn fruit oil	Fruit	0.913 - 0.919 g/mL
Sea buckthorn seed oil	Seed	0.913 - 0.919 g/mL
Krill oil	Whole	0.919 - 0.925 g/mL*
Flaxseed oil	Seed	0.928 - 0.935 g/mL
Evening Primrose Oil	Seed	0.918 - 0.930 g/mL
Olive oil	Fruit	0.908 - 0.914 g/mL
Sweet Almond Oil	Seed	0.913 - 0.919 g/mL*
Blackcurrant seed oil	Seed	0.919 - 0.926 g/mL
Chia seed oil	Seed	0.922 - 0.927 g/mL
Schizochytrium Oil (algal oil)	Whole	0.944 - 0.950 g/mL
Seal oil	Blubber	0.921 - 0.927 g/mL*
Squid oil	Whole	0.953 - 0.959 g/mL*
Wheat germ oil	Seed germ	0.922 - 0.937 g/mL
Grape Seed oil	Seed	0.921 - 0.924 g/mL