Chlorella - Chlorella vulgaris

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CHLORELLA - CHLORELLA VULGARIS (PDF Version - 53 KB) This monograph is intended to serve as a quide 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 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 June 27, 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) Chlorella vulgaris Chlorella Chlorella vulgaris Broken cell References: Proper name: Guiry and Guiry 2024; Common name: Lee et al. 2010; Tiberg et al. 1995; Source information: Becker 2007. 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) All products Source of antioxidants/Provides antioxidants (Lee et al. 2010). 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 (Lee et al. 2010). Uses based on constituent potency, provided at or above the minimum doses indicated in the dose section below. Constituents: Beta-carotene, Biotin, Folate, Iron, Magnesium, Potassium, Selenium, Vitamin A, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K1, Zinc Source of vitamin(s)/mineral(s)/vitamin(s) and mineral(s), a factor/factors in the maintenance of good health. Ingredient-specific uses or purposes as per the Natural and Non-prescription Health Products Directorate (NNHPD) Multi-Vitamin/Mineral Supplements Monograph (except uses or purposes associated with pregnancy). Constituent: Lutein Ingredient-specific uses or purposes as per the NNHPD Multi-Vitamin/Mineral Supplements Monograph. Constituent: Algal protein Source of protein for the maintenance of good health (IOM 2005; Lubitz 1963). Source of protein which helps build and repair body tissues (IOM 2005; Lubitz 1963). Source of amino acids involved in muscle protein synthesis (Misurcova 2014; IOM 2005). Constituents: L-Histidine, L-Isoleucine, L-Leucine, L-Lysine, L-Methionine, L-Phenylalanine, L-Threonine, L-Valine, L-Tryptophan Source of (an) essential amino acid(s) for the maintenance of good health (Misurcova 2014; IOM 2005). Source of (an) (essential) amino acid(s) involved in muscle protein synthesis (Misurcova 2014; IOM 2005). Constituents: L-Alanine, L-Arginine, L-Aspartic acid, L-Cysteine, L-Glutamic acid, Glycine, L-Proline, L-Serine, L-Tyrosine Source of (an) (non-essential) amino acid(s) involved in muscle protein synthesis (IOM 2005). Note: The above uses can be combined on the product label (e.g., Source of amino acids involved in muscle protein synthesis and protein for the maintenance of good health). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Not to exceed 6 grams of Chlorella broken cell per day (Lee et al. 2010). Methods of preparation: Dry standardized, Powdered standardized, Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Not to exceed 6 grams of Chlorella broken cell per day (Lee et al. 2010). AND Constituents: Beta-carotene, Biotin, Folate, Iron, Lutein, Magnesium, Potassium, Selenium, Vitamin A, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K1 and/or, Zinc As per the NNHPD Multi-vitamin/mineral supplements monograph. Constituents: Algal protein, L-Histidine, L-Isoleucine, L-Leucine, L-Lysine, L-Methionine, L-Phenylalanine, L-Threonine, L-Valine, L-Tryptophan, L-Alanine, L-Arginine, L-Aspartic acid, L-Cysteine, L-Glutamic acid, Glycine, L-Proline, L-Serine and/or L-Tyrosine As per the NNHPD Workout supplements monograph. Note: For algal protein constituent, refer to Table 2. Doses and methods of preparation for Group 1 (Proteins). Notes For a use or purpose based on a particular constituent (e.g., beta-carotene, iron, protein), the name and the amount of the constituent must be provided in the potency section of the PLA form. The minimum and maximum daily doses of the constituent must be within the range of the doses listed on the NNHPD Multi-vitamin/mineral supplements monograph or the NNHPD Workout supplements monograph. If ingredients such as vitamins and minerals are added to the product, they should be

listed as separate medicinal ingredients on the PLA form and label. In this case, it would be considered a Class II or III application. Direction(s) of use Products providing 250 mg or more of chlorella per day Take a few hours before or after taking other medications or health products (Brayfield and Cadart 2024; ASHP 2005). Constituents: Folate, Iron, Zinc As per the NNHPD Multi-vitamin/mineral supplements monograph. Duration(s) of use No statement required. Risk information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Products providing 250 mg or more of chlorella per day or 6 µg or more vitamin K per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Ohkawa et al. 1995; NNHPD Multi-vitamin/mineral supplements monograph). Products containing chlorella enriched with selenium and providing more than 70 µg of selenium per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a history of non-melanoma skin cancer (Doucha et al. 2009; NNHPD Multi-vitamin/mineral supplements monograph). Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Tiberg et al. 1995). 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. 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 raw material tolerance limit for microcystins is 1 ppm. Note that Health Canada has published an article comparing various methods available to determine microcystin concentration levels (Gilroy 2000; Lawrence et al. 2001). The medicinal ingredient must comply with the requirements outlined in the NHPID. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited ASHP 2005: American Society of Health-System Pharmacists. American Hospital Formulary Service (AHFS) Drug Information. Philadelphia (PA): Lippincott Williams and Wilkins; 2005. Becker EW. Micro-algae as a source of protein. Biotechnology Advances 2007;25:207-210. Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2024. [Accessed 2024 August 13]. Available from: https://www.medicinescomplete.com/#/browse/martindale Doucha J, Livansky K, Kotrbacek V, Zachleder V. Production of Chlorella biomass enriched by selenium and its use in animal nutrition: a review. Applied Microbiology and Biotechnology 2009;83(6):1001-1008. Gilroy DJ, Kauffman KW, Hall RA, Huang X, Chu FS. Assessing potential health risks from microcystin toxins in blue-green algae dietary supplements, 2000, 108(5):435-439. Guiry, MD, Guiry GM, AlgaeBase, World-wide publication. **National** University of Ireland, Galway. Algaebase taxon LSID: urn:lsid:algaebase.org:taxname:47342; [Accessed 2024. 2024 August 13] from: http://www.algaebase.org IOM 2005: Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fatty Acids, Cholesterol, Protein, and Amino Acids. Food and Nutrition Board, Institute of Medicine. Washington (DC): National Academy Press; 2005. Lawrence JF, Niedzwiadek B, Menard C, Lau BPY, Lewis D, Tine Kuper-Goodman B. Comparison of Liquid Chromatography/Mass Spectrometry, ELISA, and Phosphatase Assay for the Determination of Microcystins in Blue-Green Algae Products. Journal of AOAC International Vol. 84, No 4, 2001. Lee SH, Kang HJ, Lee HJ, Kang MH, Park YK. Six-week supplementation with Chlorella has favorable impact on antioxidant status in Korean male smokers. Nutrition 2010;26(2):175-183. Lubitz JA. The Protein Quality, Digestibility, and Composition of Algae, Chlorella 71105. Journal of Food Science 1963;28(2):229-232. Misurcova L, Bunka F, Vavra Ambrozova J, Machu L, Samek D, Kracmar S. Amino acid composition of algal products and its contribution to RDI. Food Chemistry 2014;151:120-125. Ohkawa S, Yoneda Y, Ohsumi Y, Tabuchi M. Warfarin therapy and chlorella. Rinsho Shinkeigaku 1995;35(7):806-807. Tiberg E, Dreborg S, Bjorksten B. Allergy to green algae (Chlorella) among children. Journal of Allergy and Clinical Immunology 1995;96(2):257-259. References reviewed Halperin SA, Smith B, Nolan C, Shay J, Kralovec J. Safety and immunoenhancing effect of a Chlorella-derived dietary supplement in healthy adults undergoing influenza vaccination: randomized, double-blind, placebo-controlled trial. Canadian Medical Association Journal 2003;169(2):111-117. Mandalam RK, Palsson BO. Elemental balancing of biomass and medium composition enhances growth capacity in high-density Chlorella vulgaris cultures. Biotechnology Bioengineering 1998;59(5):605-611. Merchant RE, Andre CA, Sica DA. Nutritional Supplementation with Chlorella pyrenoidosa for Mild to Moderate Hypertension. Journal of Medicinal Food. September 2002;5(3):141-152. Merchant RE, Andre CA. A review of recent clinical trials of the nutritional supplement Chlorella pyrenoidosa in the treatment of fibromyalgia, hypertension, and ulcerative colitis. Alternative Therapies in Health and Medicine 2001;7(3):79-91. Merchant RE, Carmack CA, Wise CM. Nutritional supplementation with Chlorella pyrenoidosa for patients with fibromyalgia syndrome: a pilot study. Phytotherapy Research 2000;14(3):167-173. Nakano S, Noguchi T, Takekoshi H, Suzuki G, Nakano M. Maternal-fetal distribution and transfer of dioxins in pregnant women in Japan, and attempts to reduce maternal transfer with Chlorella (Chlorella pyrenoidosa) supplements. Chemosphere 2005;61(9):1244-1255. Report a problem on this

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) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Products providing 250 mg or more of chlorella per day or 6 µg or more vitamin K per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Ohkawa et al. 1995; NNHPD Multi-vitamin/mineral supplements monograph). Products containing chlorella enriched with selenium and providing more than 70 µg of selenium per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a history of non-melanoma skin cancer (Doucha et al. 2009; NNHPD Multi-vitamin/mineral supplements monograph). Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (Tiberg et al. 1995).

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 the Natural Health Products Regulations.

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 raw material tolerance limit for microcystins is 1 ppm. Note that Health Canada has published an article comparing various methods available to determine microcystin concentration levels (Gilroy 2000; Lawrence et al. 2001). The medicinal ingredient must comply with the requirements outlined in the NHPID.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Chlorella vulgaris	Chlorella	Chlorella vulgaris	Broken cell