Health Canada Santé Canada

NATURAL HEALTH PRODUCT

CHLORELLA – *CHLORELLA VULGARIS*

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

- 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 April 8, 2022

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 2018; 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.

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 2002).

Constituents: L-Histidine, L-Isoleucine, L-Leucine, L-Lysine, L-Methionine, L-Phenylalanine, L-Threonine, L-Valine, Tryptophan

- Source of (an) essential amino acid(s) for the maintenance of good health (Misurcova 2014; IOM 2002).
- Source of (an) (essential) amino acid(s) involved in muscle protein synthesis (Misurcova 2014; IOM 2002).

Constituents: L-Alanine, L-Arginine, L-Aspartic acid, L-Cysteine, Glutamic acid, Glycine, L-Proline, L-Serine, L-Tyrosine

Source of (an) (non-essential) amino acid(s) involved in muscle protein synthesis (IOM 2005).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparations: Dry, Powdered, Non-standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Not to exceed 6 grams of Chlorella broken cell per day (Lee et al. 2010).

Methods of preparations: Dry standardized, Powdered standardized, Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

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, Tryptophan, L-Alanine, L-Arginine, L-Aspartic acid, L-Cysteine, Glutamic acid, Glycine, L-Proline, L-Serine and/or L-Tyrosine

As per the NNHPD Workout supplements monograph.

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 natural health products (Sweetman 2007; ASHP 2005).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to 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

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to 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 70 µg or more of selenium per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a history of non-melanoma skin cancer (Doucha et al. 2009; Current 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* (NHPR).

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.

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