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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

November 18, 2014

Proper name(s)

*Chlorella vulgaris* Beyerinck (Guiry and Guiry 2014)
Synonym: *Chlorella pyrenoidosa* Chick (Guiry and Guiry 2014; Misurcova et al. 2014)

Common name(s)

Chlorella (Lee et al. 2010; Tiberg et al. 1995)

Source material(s)

Broken cell (Becker 2007)

Route(s) of administration

Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Use(s) or Purpose(s) Statement(s) to the effect of

All products
Source of/Provides antioxidants (Lee et al. 2010).

Uses based on constituent potency, provided at or above the minimum doses indicated in the dose section below

Constituents: Vitamins and Minerals

- Source of vitamins and/or minerals for the maintenance of good health.
- Ingredient-specific uses or purposes as per the NNHPD Multi-Vitamin/Mineral Supplements Monograph.

Constituents: Proteins/Essential amino acids/Non-essential amino acids

- Source of protein which helps build and repair body tissues (IOM 2005; Lubitz 1963).
- Source of (an) (essential) amino acid(s) involved in muscle protein synthesis (Misurcova 2014; IOM 2002).
- Source of (an) essential amino acid(s) for the maintenance of good health (Misurcova 2014; IOM 2002).

Dose(s)

Subpopulation
Adults (≥ 18 years)

Quantities
Dry, Powder, Non-standardized ethanolic extracts (fluid extract, tincture), decoction
Up to 6 g per day (Lee et al. 2010).

Constituents: Vitamins and Minerals
As per the NNHPD Multi-Vitamin/Mineral Supplements Monograph

Constituents: Proteins/Essential amino acids/Non-essential amino acids
As per the NNHPD Workout Supplement 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 Product License Application 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 Product Licence Application form and label. In this case, it would be considered a Class II or III application.

Direction of use

Statement(s) to the effect of

Products providing ≥ 250 mg chlorella per day

Take a few hours before or after taking other medications or natural health products (Sweetman 2007; ASHP 2005).

Duration of use

No statement required.

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

All products

If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Products providing ≥ 250 mg chlorella per day or ≥ 6 µg vitamin K per day

If you are taking blood thinners, consult a health care practitioner prior to use (Ohkawa et al. 1995; Current NNHPD Multi-Vitamin/Mineral Supplements monograph).

Products providing chlorella enriched with selenium

If you have a history of non-melanoma skin cancer, consult a health care practitioner prior to use (Doucha et al. 2009; Current NNHPD Selenium monograph).

Contraindication(s)

No statement required.

Known adverse reaction(s)
Hypersensitivity/allergy can occur, in which case discontinue use and consult your healthcare practitioner (Tiberg et al. 1995).

**Non-medicinal ingredients**

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

**Storage conditions**

No statement required.

**Specifications**

- The finished product specifications must be established in accordance with the requirements described in the 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 2001; Lawrence et al. 2001).
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

**References cited**


References reviewed


