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: July 18, 2017

Proper name(s):

*Arthrospira platensis* Gomont (Phormidiaceae) (Guiry and Guiry 2014)

Synonyms

- *Spirulina platensis*
- *Spirulina jenneri var platensis*

Common name(s):

Spirulina (Mazokopakis et al. 2013; CNF 2010)

Source material(s):

Whole (Yu et al. 2012; CNF 2010; Dillon et al. 1995)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Dosage forms by age group:

- **Children 2 years**: The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

**Use(s) or Purpose(s):**

*All products*

- Source of/Provides antioxidants (Yu et al. 2012; Kalafati et al. 2010).
- Helps reduce symptoms of allergic rhinitis such as nasal discharge, sneezing, nasal congestion and itching (Cingi et al. 2008; Mao et al. 2005).

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

- Source of beta-carotene, a provitamin A, for the maintenance of good health (CNF 2010; IOM 2006; Shils et al. 2006).
- Source of beta-carotene, a provitamin A, to help maintain eyesight, skin, membranes and immune function (CNF 2010; IOM 2006; Shils et al. 2006).
- Source of beta-carotene, a provitamin A, to help in the development and maintenance of night vision (CNF 2010; IOM 2006; Shils et al. 2006).
- Source of beta-carotene, a provitamin A, to help in the development and maintenance of bones and teeth (CNF 2010; IOM 2006; Shils et al. 2006).
- Source of iron for the maintenance of good health (CNF 2010; IOM 2006).
- Source of iron which helps to form red blood cells and helps in their proper function (CNF 2010; IOM 2006; Shils et al. 2006).
- Source of protein for the maintenance of good health (CNF 2010; IOM 2005).
- Source of protein which helps build and repair body tissues (CFIA 2012).
- Source of (an) essential amino acid(s) for the maintenance of good health (CNF 2010; IOM 2005).
- Source of (an) (essential) amino acid(s) involved in muscle protein synthesis (CNF2010; IOM 2005).

**Note**
The recommended use or purpose, “Source of vitamin B12” is not acceptable as most vitamin B12 from this source is not bioactive (Michaelson 2009; Watanabe F. 2007, Watanabe et al. 1999).
Dose(s):

Dry, dry standardized, powder, powder standardized, extract dry, extract dry standardized, extract liquid, extract liquid standardized, fluid extract, fluid extract standardized, tincture, tincture standardized, decoction, decoction standardized.

Table 1  Minimum daily dose for spirulina and its constituents, based on recommended uses.

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Allergic rhinitis(^1)</th>
<th>No minimum spirulina dose required</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Spirulina (g/day)</td>
<td>No constituent potency required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Beta-carotene(^2) (ug/day)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Iron(^2) (mg/day)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Protein(^2) (g/day)</td>
</tr>
<tr>
<td>Children 2-4 y</td>
<td>0.3</td>
<td>180</td>
</tr>
<tr>
<td>Children 5-9 y</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Adolescents 10-14 y</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Adults and adolescents</td>
<td>2</td>
<td>390</td>
</tr>
<tr>
<td>&gt; 15 y</td>
<td></td>
<td>1.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.6</td>
</tr>
</tbody>
</table>

\(^1\) Children and adolescent minimum doses calculated as a fraction of the adult dose; Adult minimum doses supported by the following references: Cingi et al. 2008; Mao et al. 2005.

\(^2\) Children, adolescent and adult minimum doses supported by the following references: IOM 2006, 2005.

Table 2  Maximum daily dose for spirulina.

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Maximum dose (g/day)(^1,2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 2-4 y</td>
<td>1</td>
</tr>
<tr>
<td>Children 5-9 y</td>
<td>2</td>
</tr>
<tr>
<td>Adolescents 10-14 y</td>
<td>4</td>
</tr>
<tr>
<td>Adults and adolescents &gt; 15 y</td>
<td>8</td>
</tr>
</tbody>
</table>

\(^1\) Children and adolescent maximum doses calculated as a fraction of the adult dose and supported by the following references: Dia et al. 2009; Simpore et al. 2006; Samuels et al. 2002.

\(^2\) Adult maximum dose supported by the following references: Marles et al. 2011; CNF 2010; Cingi et al. 2008; Lee et al. 2008; Park et al. 2008; Baicus and Baicus 2007.

Constituents: Beta carotene/Iron

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, or protein), the name and the amount of the constituent must be provided in the potency section of the Product Licence Application form.
The minimum and maximum daily doses of the constituents 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 for use**

*Products providing ≥ 0.6 mg/day iron for children and adolescents 2-13 y, or ≥ 1.4 mg/day iron for adults*

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

**Duration of use:**

No statement required.

**Risk information:**

**Caution(s) and warning(s)**

*All products*

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

*Allergic rhinitis*

If symptoms persist or worsen, consult a health care practitioner.

**Contraindication(s)**

No statement required.

**Known adverse reaction(s)**

No statement required.

**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:

No statement required.

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 2001; Lawrence et al. 2001).
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited:


References reviewed:


