

NATURAL HEALTH PRODUCT

SPIRULINA– *SPIRULINA PLATENSIS*

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

July 31, 2018

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)
<i>Arthrospira platensis</i>	Spirulina	<i>Arthrospira platensis</i>	Whole

References: Proper name: Guiry and Guiry 2014; Common name: Mazokopakis et al. 2013, CNF 2010; Source information: Yu et al. 2012, CNF 2010, Dillon et al. 1995.

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 by age group:

Children 2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoaia et al. 2008; EMEA/CHMP 2006).

Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacoaia et al. 2008; EMEA/CHMP 2006).

Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

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)

Subpopulation(s)

As specified below.

Quantity(ies)

Methods of preparation: Dry, powder, Non-Standardized and Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Allergic rhinitis/Antioxidant

Table 2. Daily doses of spirulina for allergic rhinitis. Note that for the antioxidant claim no minimum dose of spirulina has been established; however, the maximum dose of spirulina applies.

Subpopulation(s)		Minimum dose of Spirulina (g/day) ¹	Maximum dose of Spirulina (g/day) ^{2,3}
Children	2-4 years	0.3	1
	5-9 years	0.5	2
	10-11 years	1	4
Adolescents	12-14 years	1	4
	15-17 years	2	8
Adults	18 years and older	2	8

¹Children 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.

²Children 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.

³Adult 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.

Claims based on the constituent protein

Table 3. Daily doses of algal protein (no minimum spirulina dose required).

Subpopulation(s)		Minimum dose of Algal protein (g/day) ¹	Maximum dose of Algal protein and Spirulina (g/day) ^{2,3}
Children	2-4 years	0.6	1
	5-9 years	0.9	2
	10-11 years	1.5	4

Adolescents	12-14 years	1.5	4
	15-17 years	2.6	8
Adults	18 years and older	2.6	8

¹Children, adolescent and adult minimum doses of protein supported by the following references: IOM 2006; IOM 2005.

²Children and adolescent maximum doses of spirulina calculated as a fraction of the adult dose and supported by the following references: Dia et al. 2009; Simapore et al. 2006; Samuels et al. 2002.

³Adult 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.

Claims based on the constituents Beta-carotene or Iron

Table 4. Daily doses of beta-carotene and iron (no minimum spirulina dose required).

Subpopulation(s)		Beta-carotene ¹		Iron ¹		Maximum dose of Spirulina (g/day) ^{2,3}
		Min (mcg/day)	Max (mcg/day)	Min (mg/day)	Max (mg/day)	
Children	2-3 years	180	3600	0.6	40	1
	4 years	180	5400	0.6	40	1
	5-8 years	180	5400	0.6	40	2
	9 years	180	10200	0.6	40	2
	10-11 years	180	10200	0.6	40	4
Adolescents	12-13 years	180	10200	0.6	40	4
	14 years	390	16800	1.4	45	4
	15-17 years	390	16800	1.4	45	8
Adults	18 years	390	16800	1.4	45	8
	19 years and older	390	18000	1.4	45	8

¹Children, adolescent and adult minimum and maximum doses of beta-carotene and iron supported by the NNHPD Multi-Vitamin/Mineral Supplements Monograph.

²Children and adolescent maximum doses of spirulina calculated as a fraction of the adult dose and supported by the following references: Dia et al. 2009; Simapore et al. 2006; Samuels et al. 2002.

³Adult maximum dose of spirulina 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.

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. Note that the maximum dose of protein is limited by the maximum dose of spirulina.
- ▶ 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(s) for use

Products providing 0.6 mg or more iron per day for children and adolescents 2-13 years old, or 1.4 mg or more iron per day for adults

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

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.

Allergic rhinitis

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

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 medicinal ingredient must comply with the requirements outlined in the NHPID.

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