

# Spirulina

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Spirulina Help on accessing alternative formats, such as Portable Document Format ( PDF ), Microsoft Word and PowerPoint ( PPT ) files, can be obtained in the alternate format help section. (PDF Version - 36 K) 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 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 March 28, 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) *Limnospira fusiformis* *Spirulina Limnospira fusiformis* Whole *Limnospira indica* *Spirulina Limnospira indica* Whole *Limnospira maxima* *Spirulina Limnospira maxima* Whole *Limnospira platensis* *Spirulina Limnospira platensis* Whole

References: Proper name: Guiry and Guiry 2025; Nowicka-Krawczyk et al. 2019; Common name: CNF 2024; Mazokopakis et al. 2013; Source information: Guiry and Guiry 2025; Nowicka-Krawczyk et al. 2019.

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 (Giacoa et al. 2008; EMA/CHMP 2006). Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacoa et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The 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 (Yu et al. 2012; Kalafati 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 (Yu et al. 2012; Kalafati et al. 2010). Products containing *Limnospira platensis* 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 2024; IOM 2006; Shils et al. 2006). Source of beta-carotene, a provitamin A, to help maintain eyesight, skin, membranes and immune function (CNF 2024; IOM 2006; Shils et al. 2006). Source of beta-carotene, a provitamin A, to help in the development and maintenance of night vision (CNF 2014; 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 2024; IOM 2006; Shils et al. 2006). Source of iron for the maintenance of good health (CNF 2024; IOM 2006). Source of iron which helps to form red blood cells and helps in their proper function (CNF 2024; IOM 2006; Shils et al. 2006). Source of protein for the maintenance of good health (CNF 2024; IOM 2005). Source of protein which helps build and repair body tissues (CFIA 2012). Source of essential amino acids for the maintenance of good health (CNF 2024; IOM 2005). Source of (essential) amino acids involved in muscle protein synthesis (CNF2025; IOM 2005). Notes The above uses can be combined on the product label (e.g., Source of protein for the maintenance of good health which helps build and repair body tissues). The claim "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, Powdered, Non-Standardized and Standardized Extracts (Dry extract\*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) \*Note: Solvents allowed for the method of preparation "Non-Standardized Extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Allergic rhinitis (*Limnospira platensis* only)/Antioxidants 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 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 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. 3 Adult maximum dose supported by the following references: CNF 2024; Marles et al. 2011; 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 1 Children, adolescent and adult minimum doses of protein supported by the following references: IOM 2006; IOM 2005. 2 Children and adolescent maximum doses of spirulina 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. 3 Adult maximum dose supported by the following references: CNF 2024; Marles et al. 2011; 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 1 Children, adolescent and adult minimum and maximum doses of beta-carotene and iron supported by the NNHPD Multi-Vitamin/Mineral Supplements Monograph 2 Children and adolescent maximum doses of spirulina 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. 3 Adult maximum dose of spirulina supported by the following references: CNF 2024; Marles et al. 2011; 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 doses listed on the NNHPD Multi-Vitamin/Mineral Supplements Monograph or the NNHPD Workout Supplement 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 Directions 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 health products (Brayfield and Cadart 2024). Combination rules When the medicinal ingredients listed in Table 1 are combined, the total quantity of spirulina and the total quantity of its constituents if declared must not exceed the maximum quantities listed in Tables 2, 3 and 4. 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. Allergic rhinitis Ask 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 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 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 Baicus C, Baicus A. Spirulina did not ameliorate idiopathic chronic fatigue in four N-of-1 randomized controlled trials. *Phytotherapy Research* 2007;21(6):570-573. Brayfield A, Cadart C, editors. *Martindale: The Complete Drug Reference*. London (GB): Pharmaceutical Press; 2024. [Accessed 2024 November 21]. Available from: <https://www.medicinescomplete.com/#/browse/martindale> CFIA 2025: Canadian Food Inspection Agency. Food Labelling for Industry, Ottawa (ON): Canadian Food Inspection Agency and Health Canada; 2025. [Accessed 2025 February 11]. Available from: <https://inspection.canada.ca/en/food-labels/labelling/industry> Cingi C, Conk-Dalay M, Cakli H, Bal C. The effects of spirulina on allergic rhinitis. *European Archives of Oto-Rhino-Laryngology* 2008;265(10):1219-1223. CNF 2024: Canadian Nutrient File, Food and Nutrition, Health Canada; 2024. [Accessed 2025 February 11] Available from: <https://food-nutrition.canada.ca/cnf-fce> Dia AT, Camara MD, Ndiaye P, Faye A, Wone I, Gueye BC, Seck I, Diongue M. Contribution of supplementation by spiruline to the performance of school children in an introductory course in Dakar (Senegal). *Sante Publique* 2009;21(3):297-302. EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal

Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population; 2006. [Accessed 2025 February 11]. Available from: [https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf) Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101. Guiry MD, Guiry GM. 2025. AlgaeBase. World-wide electronic publication, University of Galway. Algaebase taxon LSID: urn:lsid:algaebase.org:taxname:47342; 2025. [Accessed 2025 February 11]. 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Increasing gammalinolenic acid content in *Spirulina platensis* using fatty acid supplement and light-dark illumination. *Journal of applied phycology* 2011:1-8. Facciola S. *Cornucopia II. A source book of edible plants*. Vista (CA): Kampong Publications; 1998. Gardner Z, McGuffin M, editors. *American Herbal Products Association's Botanical Safety Handbook*. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013. Katz M, Levine AA, Kol-Degani H, Kav-Venaki L. A compound herbal preparation (CHP) in the treatment of children with ADHD: a randomized controlled trial. *Journal of Attention Disorders* 2010;14(3):281-291. Mazokopakis EE, Karefilakis CM, Tsartsalis AN, Milkas AN, Ganotakis ES. Acute rhabdomyolysis caused by Spirulina (*Arthrospira platensis*). *Phytomedicine*. 2008;15(6-7):525-527. Pedersen

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## **DOSAGE FORM(S)**

Acceptable dosage forms by age group: Children 2 years:The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMA/CHMP 2006). Children 3-5 years:The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:The 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.

## **DOSE(S)**

Source of beta-carotene, a provitamin A, for the maintenance of good health (CNF 2024; IOM 2006; Shilset al.2006).Source of beta-carotene, a provitamin A, to help maintain eyesight, skin, membranes and immune function (CNF 2024; IOM 2006; Shilset al.2006).Source of beta-carotene, a provitamin A, to help in the development and maintenance of night vision (CNF 2014; IOM 2006; Shilset al.2006).Source of beta-carotene, a provitamin A, to help in the development and maintenance of bones and teeth (CNF 2024; IOM 2006; Shilset al.2006).Source of iron for the maintenance of good health (CNF 2024; IOM 2006).Source of iron which helps to form red blood cells and helps in their proper function (CNF 2024; IOM 2006; Shilset al.2006).Source of protein for the maintenance of good health (CNF 2024; IOM 2005).Source of protein which helps build and repair body tissues (CFIA 2012).Source of essential amino acids for the maintenance of good health (CNF 2024; IOM 2005).Source of (essential) amino acids involved in muscle protein synthesis (CNF2025; IOM 2005).

## **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. Allergic rhinitis Ask 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations.

## 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 medicinal ingredient must comply with the requirements outlined in theNHPID. EXAMPLE OF PRODUCT FACTS:

## REFERENCES

Route of administration Oral

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Limnospira fusiformis	Spirulina	Limnospira fusiformis	Whole
Limnospira indica	Spirulina	Limnospira indica	Whole
Limnospira maxima	Spirulina	Limnospira maxima	Whole
Limnospira platensis	Spirulina	Limnospira platensis	Whole

	Maximum dose of Spirulina (g/day) <sup>2,3</sup>								
	0.3	1							
	0.5	2 10-11 years	1 4 Adolescents	12-14 years	1 4 15-17 years	2 3 Adults			
	1	4							
	1	4							
	2	8							
	18 years and older	2 8							
	18 years and older	2 8							

[illegible]

0.6	1									
0.9	2	10-11 years	1.5	4 Adolescents	12-14 years	1.5	4 15-17 years	2.6	8 Adults	
1.5	4									
1.5	4									
2.6	8									
18 years and older	2.6	8								
18 years and older	2.6	8								

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