

NATURAL HEALTH PRODUCT

SOY FLOUR

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

September 29, 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)	Preparation(s)
<i>Glycine max</i>	▶ Soybean Flour ▶ Soy Flour	<i>Glycine max</i>	Seed	Dry
	▶ Defatted soybean flour ¹ ▶ Defatted soy flour ¹	<i>Glycine max</i>	Seed	Dry

References: Proper name: USDA 2019; Common names: USDA 2019, Tomar and Shiao 2008; Source information: USDA 2019, Tomar and Shiao 2008.

¹Defatted flour refers to preparations where the oil has been removed.

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)

- ▶ Source of antioxidants/Provides antioxidants (Wang et al. 2013; Liu et al. 2005).
- ▶ 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 (Wang et al. 2013; Liu et al. 2005).
- ▶ Source of protein (for the maintenance of good health) (CFIA 2016).
- ▶ Source of protein which helps build and repair body tissues (CFIA 2016).
- ▶ Source of (an) (non-essential) amino acid(s) involved in muscle protein synthesis (IOM 2005).
- ▶ Source of (an) (essential) amino acid(s) involved in muscle protein synthesis (IOM 2005).
- ▶ Source of (an) essential amino acid(s) for the maintenance of good health (IOM 2005).

The following combined use(s) or purpose(s) is/are also acceptable:

Source of (an) essential amino acid(s) involved in muscle protein synthesis and for the maintenance of good health (IOM 2005).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Antioxidants

Methods of preparation: Powder; Defatted, ground

Not to exceed 8 grams of soy flour and/or defatted soy flour, per day (Tomar and Shiao 2008; Travis et al. 2008).

Source of Protein

Method of preparation: Defatted, ground

5.5 – 8 grams of defatted soy flour, per day (CNF 2015; Travis et al. 2008; IOM 2005).

Method of preparation: Powder

7.5 – 8 grams of soy flour, per day (CNF 2015; Travis et al. 2008; IOM 2005).

Note: If soy flour and defatted soy flour are combined, 7.5 grams should be used as the minimum total daily dose and 8 grams as the maximum total daily dose.

Source of (essential) amino acid(s) involved in muscle protein synthesis/for the maintenance of good health

Method of preparation: Defatted, ground

5.5 – 8 grams of defatted soy flour, per day (CNF 2015; Travis et al. 2008; IOM 2005).

Method of preparation: Powder

7.5 – 8 grams of soy flour, per day (CNF 2015; Travis et al. 2008; IOM 2005).

Note: If soy flour and defatted soy flour are combined, 7.5 grams should be used as the minimum total daily dose and 8 grams as the maximum total daily dose.

OR

Method of preparation: Standardized Powder

Essential amino acids	Minimum dose of amino acid (milligrams/day) ¹	Maximum dose of Soy flour and/or Defatted soy flour (grams/day) ²
Histidine	49 mg	8 g
Isoleucine	66.5 mg	
Leucine	147 mg	
Lysine	133 mg	
Methionine	66.5 mg	
Phenylalanine	115.5 mg	
Threonine	70 mg	
Tryptophan	17.5 mg	
Valine	84 mg	

¹Minimum doses have been calculated as 5% of each specific amino acid Recommended Dietary Allowance with a reference weight of 70 kg (IOM 2005).

²Maximum dose (CNF 2015; Tomar and Shiao 2008; Travis et al. 2008; IOM 2005).

Source of (non-essential) amino acids involved in muscle protein synthesis

Method of preparation: Defatted, ground

5.5 – 8 grams of defatted soy flour, per day (CNF 2015; Travis et al. 2008; IOM 2005).

Method of preparation: Powder

7.5 – 8 grams of soy flour, per day (CNF 2015; Travis et al. 2008; IOM 2005).

Note: If soy flour and defatted soy flour are combined, 7.5 grams should be used as the minimum total daily dose and 8 grams as the maximum total daily dose.

OR

Method of preparation: Standardized Powder

Non-Essential amino acids	Minimum dose of amino acid (milligrams/day) ¹	Maximum dose of Soy flour and/or Defatted soy flour (grams/day) ²
Alanine	181.5 mg	8 g
Arginine	208.5 mg	
Aspartic acid	325 mg	
Glutamic acid	750 mg	
Glycine	160 mg	
Proline	259.5 mg	
Serine	175.5 mg	
Tyrosine	139 mg	

¹Minimum doses have been calculated as 5% of each specific amino acid Mean Intake with a reference weight of 70 kg (IOM 2005).

²Maximum dose (CNF 2015; Tomar and Shiao 2008; Travis et al. 2008; IOM 2005).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

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

References cited

CNF 2015: Canadian Nutrient File. Canadian Nutrient File, Ottawa (ON): Food and Nutrition, Health Canada. [Accessed 2019 May 27]. Available from: <https://food-nutrition.canada.ca/cnf-fce/switchlocale.do?lang=en&url=t.search.recherche>

CFIA 2016: Canadian Food Inspection Agency. Food Labelling for Industry, Ottawa (ON): Canadian Food Inspection Agency and Health Canada. Internet. [Accessed 2019 June 17]. Available from: <http://www.inspection.gc.ca/food/requirements/labelling/industry/eng/1383607266489/1383607344939>

IOM 2005: Institute of Medicine of the National Academies. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Food and Nutrition Board, [Accessed 2019 June 3]. Available from: https://www.nal.usda.gov/sites/default/files/fnic_uploads/energy_full_report.pdf

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Travis RC, Allen NE, Appleby PN, Spencer EA, Roddam AW, Key TJ. A prospective study of vegetarianism and isoflavone intake in relation to breast cancer in British women. *International Journal of Cancer* 2008;122:705-10.

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