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 (NHP) 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

December 8, 2015

Proper name(s), Common name(s) and Source material(s)

Table 1: Proper name(s), common name(s) and source material(s)

<table>
<thead>
<tr>
<th>Proper name(s)¹</th>
<th>Common name(s)¹,²</th>
<th>Source material(s)¹,²</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Glycine max</em> (L.) Merr.</td>
<td>Soy flour</td>
<td>Seed (Bean)</td>
</tr>
<tr>
<td></td>
<td>Soybean flour</td>
<td></td>
</tr>
<tr>
<td><em>Glycine max</em> (L.) Merr.</td>
<td>Defatted soy flour³</td>
<td>Seed (Bean)</td>
</tr>
<tr>
<td></td>
<td>Defatted soybean flour³</td>
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</tbody>
</table>

¹. USDA 2006
². Tomar and Shiao 2008
³. Defatted flour refers to preparations where the oil has been removed.

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, beverages or bulk flour intended for food preparation.
Use(s) or Purpose(s) Statement(s) to the effect of

All products

- 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 (an) (essential) amino acid(s) involved in muscle protein synthesis (IOM 2002)*.
- Source of (an) essential amino acid(s) for the maintenance of good health (IOM 2002)*.

*Note
For these claims, individual amino acid quantity must be indicated on the PLA in the “Activity” section and on the label.

Products containing defatted soy flour

- Source of protein (for the maintenance of good health) (CFIA 2012).
- Source of protein which helps build and repair body tissues (CFIA 2012).

Dose(s) Statement(s) to the effect of

Subpopulation

Adults (≥ 18 years)

Quantity

Antioxidant

Powder, defatted, ground

Up to 8 g soy flour per day (Tomar and Shiao 2008; Travis et al. 2008).

Source of Protein: Defatted soy flour only

Powder, defatted, ground

5.5 – 8 g defatted soy flour per day (CNF 2010; Travis et al. 2008; IOM 2002)

Source of Amino acid(s)

As per the doses indicated in the Natural and Non-prescription Health Products Directorate (NNHPD) Workout Supplement monograph.
Directions for use

No statement required.

Duration 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

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

References cited
References reviewed


Doerge DR. Bioavailability of soy isoflavones through placental/lactational transfer and soy food. Toxicology and Applied Pharmacology 2011;254(2):145-