Soybean Extracts and Isolates

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SOYBEAN EXTRACTS AND ISOLATES 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 - 231 KB) 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 September 27, 2024 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 ingredient(s) Source material(s) Part(s) 4',5,7-Trihydroxyisoflavone 5,7-Dihydroxy-3-(4-hydroxyphenyl)-4H-1-benzopyran-4-one Genistein Genistein Glycine max Seed 7-(beta-D-glucopyranosyloxy)-3-(4- hydroxyphenyl)-4H-1-Benzopyran-4-one 7-O-beta-D-Glucopyranoside Genistein 7-glucoside Genistin Genistin Glycine max Seed Glycine max Black soya bean Da dou Soy Soya Soyabean Soybean N/A Glycine max Seed Soy isoflavone extract Soy isoflavone extract N/A Glycine max Seed Soy protein concentrate Soy protein concentrate N/A Glycine max Seed Soy protein isolate 1 Soy protein isolate N/A Glycine max Seed References: Proper names: NHPID 2024, USDA 2024, Evans et al. 2007, Newton et al. 2006, Roudsari et al. 2005, Arjamandi et al. 2003, Yamori et al. 2002, Alekel et al. 2000, Scambia et al. 2000, Upmalis et al. 2000 Wangen et al. 2000, Potter et al. 1998; Common names: NHPID 2024, Evans et al. 2007, Newton et al. 2006, Roudsari et al. 2005, Arjamandi et al. 2003, Yamori et al. 2002, Alekel et al. 2000, Wangen et al. 2000, Potter et al. 1998; Source information: NHPID 2024, USDA 2024, D'Anna et al. 2007, Evans et al. 2007, Nahas et al. 2007, Newton et al. 2006, Ye et al. 2006, Roudsari et al. 2005, Crisafulli et al. 2004, Harkness et al. 2004, Kreijkamp-Kaspers et al. 2004, Arjamandi et al. 2003, Uesugi et al. 2003, Han et al. 2002, Albert et al. 2002, Faure et al. 2002, Yamori et al. 2002, Alekel et al. 2000, Wangen et al. 2000, Albertazzi et al. 1998, Potter et al. 1998. 1 For isolate, the potency information should be equivalent to 90% or more protein on a dry weight basis. 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) Helps to attenuate/reduce/decrease bone (mineral density (BMD)) loss in postmenopausal women when used in conjunction with adequate amounts of calcium and vitamin D (Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998). May reduce severe and frequent menopausal symptoms (such as hot flashes and/or night sweats) (D'Anna et al. 2007; Nahas et al. 2007; Williamson-Hughes et al. 2006; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998). Dose(s) Subpopulation(s) Perimenopausal women; Postmenopausal women (D'Anna et al. 2007; Nahas et al. 2007; Crisafulli et al. 2004; Albert et al. 2002; Faure et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998). Quantity(ies) Reduction of BMD loss Glycine max, Soy isoflavone extract Methods of preparation: Standardized extracts 75 - 125 milligrams of total Aglycone Isoflavone Equivalents (AIE), per day (Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998). Soy protein concentrate, Soy protein isolate Methods of preparation: Standardized extracts 75 - 125 milligrams of total AIE, per day; Not to exceed 35 grams of soy protein concentrate and/or isolate, per day (CNF 2024; Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; CPS 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998). Genistein, Genistin 75 - 125 milligrams of total AIE, per day (Marini et al. 2007; Newton et al. 2006; Ye et al. 2006; Chen et al. 2004; Kreijkamp-Kaspers et al. 2004; Lydeking et al. 2004; Uesugi et al. 2003; Alekel et al. 2000; Potter et al. 1998). Reduction of menopausal symptoms Glycine max, Soy isoflavone extract Methods of preparation: Standardized extracts 30 - 125 milligrams of total AIE with a minimum of 15 milligrams of AIE from genistein and/or genistin, per day (D'Anna et

al. 2007; Nahas et al. 2007; Williamson-Hughes et al. 2006; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998). Soy protein concentrate, Soy protein isolate 30 - 125 milligrams of total AIE with a minimum of 15 milligrams of AIE from genistein and/or genistin, per day; Not to exceed 35 grams of soy protein concentrate and/or isolate, per day (CNF 2024; D'Anna et al. 2007; Nahas et al. 2007; Williamson-Hughes et al. 2006; CPS 2004; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998). Genistein, Genistin 15 - 125 milligrams of total AIE, per day (D'Anna et al. 2007; Nahas et al. 2007; Williamson-Hughes et al. 2006; Crisafulli et al. 2004; Albert et al. 2002; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998). Direction(s) for use Take a few hours before or after taking other medications or health products (Sweetman 2007; ASHP 2005). Duration(s) of Use Reduction of BMD loss Use for at least 6 months to see beneficial effects (Ye et al. 2006; Harkness et al. 2004; Alekel et al. 2000; Potter et al. 1998). Reduction of menopausal symptoms Use for at least 2 weeks to see beneficial effects (D'Anna et al. 2007; Nahas et al. 2007; Crisafulli et al. 2004; Han et al. 2002; Scambia et al. 2000; Upmalis et al. 2000; Albertazzi et al. 1998). All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 1 year (Tomar and Shiao 2008; BfR 2007; Duffy et al. 2007; Palacios et al. 2007; Unfer et al. 2004; Petrakis et al. 1996). 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 not up-to-date on mammograms and gynaecological evaluations (Tomar and Shiao 2008; BfR 2007; Duffy et al. 2007; Palacios et al. 2007; Unfer et al. 2004; Petrakis et al. 1996). Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners or any hormone replacement therapy (Rios et al. 2008; BfR 2007; Messina and Redmond 2006; ASHP 2005; Izzo et al. 2005; Mills and Bone 2005; Franco et al. 2004; Mazer 2004; Murray et al. 2003; Cambria-Keily 2002; Bell and Ovalle 2001; IOM 2001; Hansten et al. 1997; Petrakis et al. 1996). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a liver disorder or a history of hormonal or gynaecological disease (NIH 2022; Cecchi et al. 2009; Chandrareddy et al. 2008; Gasteyger et al. 2008; Tomar and Shiao 2008; Jefferson et al. 2007; Palacios et al. 2007; Kaari et al. 2006; Noel et al. 2006; Maskarinec et al. 2004a; Maskarinec et al. 2004b; Unfer et al. 2004; Borghi-Scoazec et al. 2002; Wu et al. 2000; Duncan et al. 1999b; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996). Contraindication(s) Do not use if you have or had breast cancer or tumours or a predisposition to breast cancer, as indicated by an abnormal mammogram or biopsy, or a family member with breast cancer (Helferich et al. 2008; Tomar and Shiao 2008; BfR 2007; Duffy et al. 2007; Kaari et al. 2006; Nikander et al. 2005; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996). Known adverse reaction(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if new symptoms develops such as breast pain, a recurrence of menstruation, uterine spotting or liver-related symptoms (e.g. abdominal pain, jaundice, dark urine) (Chandrareddy et al. 2008; Martinez and Lewi 2008; Palacios et al. 2007; Olawaiye et al. 2005; Albert et al. 2002; Han et al. 2002; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996). 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. For an accurate measure of specific isoflavones in AIE, follow the methods outlined in AOAC 2008.03 (Collison 2008). EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Albert A, Altabre C, Baró F, Buendía E, Cabero A, Cancelo MJ, Castelo-Branco C, Chantre P, Duran M, Haya J, Imbert P, Julía D, Lanchares JL, Llaneza P, Manubens M, Miñano A, Quereda F, Ribes C, Vázquez F. 2002. Efficacy and safety of a phytoestrogen preparation derived from Glycine max (L.) Merr in climacteric symptomatology: a multicentric, open, prospective and non-randomized trial. Phytomedicine 9(2):85-92. 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MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

DOSAGE FORM(S)

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.

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 not up-to-date on mammograms and gynaecological evaluations (Tomar and Shiao 2008; BfR 2007; Duffy et al. 2007; Palacios et al. 2007; Unfer et al. 2004; Petrakis et al. 1996).Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners or any hormone replacement therapy (Rios et al. 2008; BfR 2007; Messina and Redmond 2006; ASHP 2005; Izzo et al. 2005; Mills and Bone 2005; Franco et al. 2004; Mazer 2004; Murray et al. 2003; Cambria-Keily 2002; Bell and Ovalle 2001; IOM 2001; Hansten et al. 1997; Petrakis et al. 1996).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a liver disorder or a history of hormonal or gynaecological disease (NIH 2022; Cecchi et al. 2009; Chandrareddy et al. 2008; Gasteyger et al. 2008; Tomar and Shiao 2008; Jefferson et al. 2007; Palacios et al. 2007; Kaari et al. 2006; Noel et al. 2006; Maskarinec et al. 2004a; Maskarinec et al. 2004b; Unfer et al. 2004; Borghi-Scoazec et al. 2002; Wu et al. 2000; Duncan et al. 1999b; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996). Contraindication(s) Do not use if you have or had breast cancer or tumours or a predisposition to breast cancer, as indicated by an abnormal mammogram or biopsy, or a family member with breast cancer (Helferich et al. 2008; Tomar and Shiao 2008; BfR 2007; Duffy et al. 2007; Kaari et al. 2006; Nikander et al. 2005; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996). Known adverse reaction(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if new symptoms develops such as breast pain, a recurrence of menstruation, uterine spotting or liver-related symptoms (e.g. abdominal pain, jaundice, dark urine) (Chandrareddy et al. 2008; Martinez and Lewi 2008; Palacios et al. 2007; Olawaiye et al. 2005; Albert et al. 2002; Han et al. 2002; Hargreaves et al. 1999; McMichael-Phillips et al. 1998; Petrakis et al. 1996).

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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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.For an accurate measure of specific isoflavones in AIE, follow the methods outlined in AOAC 2008.03 (Collison 2008).

REFERENCES

1For isolate, the potency information should be equivalent to 90% or more protein on a dry weight basis.

Proper name(s)	Common name(s)	Source information		
Source ingredient(s)	Source material(s)	Part(s)		
4',5,7-Trihydroxyisoflavone	5,7-Dihydroxy-3-(4-hydroxyphenyl)-4H-1-benzopyran-4-one	Genistein	Glycine max	Seed
7-(beta-D-glucopyranosyloxy)-3-(4- hydroxyphenyl)-4H-1-benzopyran-4-one	7-O-beta-D-Glucopyranoside Genistein 7-glucoside	Genistin	Glycine max	Seed
Glycine max	Black soya beanDa douSoySoyaSoyabeanSoybean	N/A	Glycine max	Seed
Soy isoflavone extract	Soy isoflavone extract	N/A	Glycine max	Seed
Soy protein concentrate	Soy protein concentrate	N/A	Glycine max	Seed
Soy protein isolate1	Soy protein isolate	N/A	Glycine max	Seed

Isoflavone (1 mg)	Aglycone Isoflavone Equivalent (mg AIE) quantity
Genistein	1.0
Genistin	0.625
Malonyl genistin	0.521
Acetyl genistin	0.570
Daidzein	1.0
Daidzin	0.611
Malonyl daidzin	0.506
Acetyl daidzin	0.555
Glycitein	1.0
Glycitin	0.637
Malonyl glycitin	0.534
Acetyl glycitin	0.582