

NATURAL HEALTH PRODUCT

INULIN

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

October 29, 2021

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		Preparation(s)
		Source material(s)	Part(s)	Treparation(s)
Inulin	Inulin	Cichorium intybus	Root	Isolate
		Helianthus tuberosus	Tuber	

References: Proper name: CFIA 2016, IOM 2005; Common name: CFIA 2016, IOM 2005; Source information: USDA 2019a,b, CFIA 2016, IOM 2005, McGuffin et al. 2000.

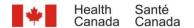
Route of administration

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 fiber for the maintenance of good health (CFIA 2016; FCC 8 2012; IOM 2005).
- ▶ Helps support and maintain a healthy digestive system (CFIA 2016; FCC 8 2012; IOM 2005).
- ▶ Helps stimulate the growth of healthy bacteria (such as bifidobateria) in the intestine/gut (Marteau et al. 2011; Roberfroid 2007a; Menne et al. 2000; Gibson et al. 1995).
- ▶ Prebiotic (Marteau et al. 2011; Roberfroid 2007a,b; Menne et al. 2000; Gibson et al. 1995).
- ▶ Helps provide gentle relief of constipation and/or irregularity (Marteau et al. 2011; IOM 2005; Kleessen et al. 1997).

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

Prebiotic which helps stimulate the growth of healthy bacteria (such as bifidobacteria) in the intestine/gut (Marteau et al. 2011; Roberfroid 2007a,b; Menne et al. 2000; Gibson et al. 1995).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Source of fiber, healthy digestive system, constipation/irregularity

2 - 15 grams of Inulin, per day (Kolida and Gibson 2007; IOM 2005; Menne et al. 2000; Coussement 1999).

Prebiotic, healthy bacteria

5 - 15 grams of Inulin, per day (Kolida and Gibson 2007; Menne et al. 2000; Coussement 1999).

Direction(s) for use

Products providing 5 g or more of Inulin, per dose

Powder

- ▶ Mix well with at least 240 milliliters of liquid (e.g. water, milk, fruit juice or similar aqueous beverage). Stir briskly and drink immediately (Pray 2006).
- ▶ Take 2 hours before or after taking other medications or natural health products (Pray 2006).
- Optional: Take during the day (not immediately prior to bedtime) (Sweetman 2007).

Other dosage forms

► Take with at least 240 milliliters of liquid (e.g. water, milk, fruit juice or similar aqueous





beverage) (Pray 2006).

- ▶ Take 2 hours before or after taking other medications or natural health products (Pray 2006).
- ▶ *Optional*: Take during the day (not immediately prior to bedtime) (Sweetman 2007).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Products for constipation/irregularity

- ► Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or if laxative effect does not occur within 7 days (Pray 2006).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have symptoms such as abdominal pain, nausea, vomiting or fever (as these could be signs of other serious conditions) (Pray 2006).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are experiencing a sudden change in bowel habits that has persisted for more than 2 weeks, undiagnosed rectal bleeding, or have failed to defecate following the use of a laxative product (Pray 2006).

Products providing 5 g or more of Inulin, per dose

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have diabetes (Pray 2006).

Contraindication(s)

No statement required.

Known adverse reaction(s)

All products

Stop use if hypersensitivity/allergy occurs (Brinker 2010; Hendler and Rorvik 2008; Franck et al. 2005; Gay-Crosier et al. 2000).

Products providing 5 g or more of Inulin, per day

May cause temporary gas and/or bloating (Marteau et al. 2011; Kolida and Gibson 2007; Menne et al. 2000; Coussement 1999; Klessen et al. 1997).





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

Store in a well-closed container at room temperature (USP 35 2012).

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

Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

CFIA 2016: Canadian Food Inspection Agency, Food Labelling for Industry, Chapter 6: Elements Within the Nutrition Facts Table Section 6.8.1 Dietary Fibre. [Accessed 2019 June 26]. Available from: http://www.inspection.gc.ca/food/requirements-and-guidance/labelling/industry/eng/1383607266489/1383607344939

Coussement PAA 1999. Inulin and Oligofructose: safe intakes and legal status. The Journal of Nutrition 1999;129:1412S-1417S.

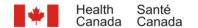
FCC 8: Food Chemicals Codex. Eighth edition. Rockville (MD): The United States Pharmacopeial Convention; 2012.

Franck P, Moneret-Vautrin DA, Morisset M, Kanny G, Mégret-Gabeaux ML, Olivier JL. Anaphylactic reaction to inulin: first identification of specific IgEs to an inulin protein compound. International Archives of Allergy and Immunology 2005;136:155-158.

Gay-Crosier F, Schreiber G, Huaser C. Anaphylaxis from inulin in vegetables and processed food. The New England Journal of Medicine 2000;342(18):1372.

Gibson GR, Beatty ER, Wang X, Cummings JH. Selective stimulation of bifidobacteria in the human colon by oligofructose and inulin. Gastroenterology 1995;108(4):975-82. Hendler SS, Rorvik DM, editors. Physician Desk References (PDR) for Nutritional Supplements,





2nd edition. Montvale (NJ): Thomson Reuters, 2008.

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 26]. Available from: https://www.nap.edu/read/10490/chapter/12#680

Kleessen B, Sykura B, Zunft H-J, Blaut M. Effects of inulin and lactose on fecal microflora, microbial activity, and bowel habit in elderly constipated persons. American Journal of Clinical Nutrition 1997;65(5):1397-1402.

Kolida S, Gibson GR. 2007. Prebiotic capacity of inulin-type fructans. The Journal of Nutrition 2007;137:2503S-2506S.

Marteau P, Jacobs H, Cazaubiel M, Signoret C, Prevel J-M, Housez B. Effects of chicory inulin in constipated elderly people: a double-blind controlled trial. International of Food Sciences and Nutrition 2011;62(2):164-170.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

Menne E, Guggenbuhl, Roberfroid M. Fn-type chicory inulin hydrolysate has a prebiotic effect in humans. Journal of Nutrition 2000;130:1197-1199.

Pray WS. Non-Prescription Product Therapeutics, 2^{nd} edition. New York (NY): Lippincott Williams & Wilkins; 2006.

Ramnani P, Gaudier E, Bingham M, van Bruggen P, Tuohy KM, Gibson GR. Prebiotic effect of fruit and vegetable shots containing Jerusalem artichoke inulin: a human intervention study. British Journal of Nutrition 2010;104(2):233-240.

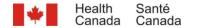
Roberfroid MB. Inulin-type fructans: functional food ingredients. The Journal of Nutrition 2007a;137:2493S-2502S.

Roberfroid M. Prebiotics: The Concept Revisited. The Journal of Nutrition 2007b;137:830S-837S.

USDA 2019a: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. *Cichorium intybus* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 June 26]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx

USDA 2019b: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. *Helianthus tuberosus* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 June 26]. Available from: https://npgsweb.ars-





grin.gov/gringlobal/taxon/taxonomysimple.aspx

USP 35: United States Pharmacopeia and the National Formulary (USP 35 - NF 30). Rockville (MD): The United States Pharmacopeial Convention; 2012.

References reviewed

BHC 1992: Bradley PR, editor. British Herbal Compendium Volume 1: A Handbook of Scientific Information on Widely Used Plant Drugs—Companion to Volume 1 of the British Herbal Pharmaocopeia. Bournemouth (GB): British Herbal Medicine Association; 1992.

Brighenti F, Casiraghi MC, Canzi E, Ferrari A. Effect of consumption of a ready-to-eat breakfast cereal containing inulin on the intestinal milieu and blood lipids in healthy male volunteers. European Journal of Clinical Nutrition 1999;53(9):726-33.

Causey JL, Feirtag JM, Gallaher DD, Tungland BC, Slavin JL. Effects of dietary inulin on serum lipids, blood glucose and the gastrointestinal environment in hypercholesterolemic men. Nutrition Research 2000;20:191-201.

Den Hond E, Geypens B, Ghoos Y. Effect of high performance chicory inulin on constipation. Nutrition Research 2000;20(5):731-736.

ESCOP 2003: E/S/C/O/P Monographs: The Scientific Foundation for Herbal Medicinal Products. 2nd edition. Exeter (GB): ESCOP, the European Scientific Cooperative on Phytotherapy in collaboration with Georg Thieme Verlag and Thieme; 2003.

Kim SH, Lee DH, Meyer D, Supplementation of infant formula with native inulin has a prebiotic effect in formula-fed babies. Asia Pacific Journal of Clinical Nutrition 2007;16(1):172-177.

Pourghassem GB, Dehghan P, Aliasgharzadeh A, Asghari J-AM. Effects of high performance inulin supplementation on glycemic control and antioxidant status in women with type 2 diabetes. Diabetes Metabolism Journal 2013;37(2):140-148.

Rao AV. Dose-Response effects of inulin and oligofructose on intestinal bifidogenesis effects. Journal of Nutrition 1999;129:1442S-1445S.

Roberfroid MB, Van Loo JAE, Gibson GR. The bifidogenic nature of chicory inulin and its hydrolysis products journal of nutrition 1998;128:11-19.

Szajewska H, Wizman Z, Abu-Zekry M, Kekez A, Braegger C, Kolacek S, Micetic-Turk D, Ruszczynski M, Vukavic T. Inulin and fructo-oligosaccharides for the prevention of antibiotic-associated diarrhea in children: report by the ESPHGAN working group on probiotics and prebiotics. Journal of Pediatric Gastroenterology and Nutrition 2012;54(6):828-829.

Van Dokkum W, Wezendonk B, Srikumar TS, van den Heuvel EGHM. Effect of nondigestible oligosaccharides on large-bowel functions, blood lipid concentrations and glucose absorption in





young healthy male subjects. European Journal of Clinical Nutrition 1999;53(1):1-7.

Yap WKW, Mohamed S, Jamal MH, Meyer D, Manap YA. Changes in infant faecal characteristics and microbiota by inulin supplementation. Journal of Clinical Biochemistry Nutrition 2008;43:159-166.

WHO 1999: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 1. Geneva (CH): World Health Organization; 1999.