Whey products

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WHEY PRODUCTS 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 - 217 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 November 29, 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 material(s) Part(s) Whey protein isolate 1 Whey protein isolate Bos taurus Capra hircus Milk Whey protein concentrate Whey protein concentrate Reduced lactose whey Whey, reduced lactose Reduced lactose whey Whey, reduced lactose Reduced minerals whey Whey, reduced minerals Reduced minerals whey Whey, reduced minerals Whey Whey Whey protein hydrolysate Whey protein hydrolysate References: Proper names: US FDA 2024; FCC 2023; Common names: US FDA 2024; FCC 2023; Source information: ITIS 2024. 1 For isolates, 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) Products standardized to protein Source of (all) essential amino acids (i.e. histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine) for the maintenance of good health (CNF 2023; Potier and Tomé 2008). Source of branched chain amino acids for the maintenance of good health (CNF 2023; Potier and Tomé 2008). Source of (essential) amino acids involved in muscle protein synthesis (CNF 2023; IOM 2005). (Excellent) Source of protein for the maintenance of good health (CFIA 2022). (Excellent) Source of protein which helps build and repair body tissues (CFIA 2022). (Excellent) Source of protein which helps build antibodies (CFIA 2022). Products standardized to protein and minerals Source of ((the) mineral(s)) calcium/magnesium/phosphorus/potassium/(and) zinc for the maintenance of good health (CNF 2023; IOM 2005). Note: The above uses can be combined on the product label (e.g., Source of protein which helps build and repair body tissues and build antibodies). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) The potency of protein on an "as is" weight basis is required to be indicated on the PLA form and label. Source of protein 2.6-90 grams of protein per day (CFIA 2022) Excellent source of protein 16-90 grams of protein per day (CFIA 2022) Source of amino acids/branched chain amino acids 3-90 grams of protein per day (CFIA 2022) Source of minerals Not to exceed 90 grams of protein per day (CFIA 2022) and Table 2. Daily dose requirements for minerals in whey preparations Minerals 1 Minimum dose (mg/day) Maximum dose (mg/day) Calcium 65 1,500 Magnesium 20 500 Phosphorus 62 2,000 Potassium 100 779 Zinc 0.7 50 1 Quantities for potassium are based on IOM 2005. Quantities for other minerals are based on the NNHPD Multi-vitamin/Mineral Supplements Monograph. Notes The use “ Source of mineral(s) xxx ” is only acceptable if indicated minerals are present at dosages at or above the minimum daily doses and not more than the maximum daily doses as listed in Table 2 above. In order to have a use for a particular mineral, the medicinal ingredient must list the respective mineral as potency on the PLA form and label. Direction(s) for use Take a few hours before or after taking other medications or health products (Sweetman 2011; Jung et al. 1997). Permitted combinations Medicinal ingredients listed in Table 1 can be combined; however, the total amount of protein and minerals must meet the maximal quantities listed in this monograph. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products Contains milk by-products (CFIA 2022; Wal 2002). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Products providing more than 30 g protein, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a liver or kidney disorder (Shils et al. 2006; Bell 2000). Contraindication(s) Products providing 100 mg or more potassium, per day Do not use if you are taking other potassium-containing salt-substitutes or supplements

(Sweetman 2011). Known adverse reaction(s) Products providing more than 30 g protein, per day When using this product you may experience gastrointestinal discomfort/disturbance(s) (Micke et al. 2002). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Whey proteins, especially powders meant to be mixed with a liquid, often require lecithin to act as a dispersing/emulsifying agent. If present, lecithin must be added as a non-medicinal ingredient. 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. The medicinal ingredient proper name should be determined by the potency of whey protein on a dry weight basis as published in the Food and Chemical Codex (FCC 2023). Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Bell SJ. Whey Proteins Concentrates With and Without Immunoglobulins: A Review. Journal of Medicinal Food. 2000 Spring;3(1):1-13. CFIA 2022: Canadian Food Inspection Agency. Food Labelling for Industry. Ottawa (ON). [Accessed 2024 January 12]. Available from: https://inspection.canada.ca/food-labels/labelling/industry/eng/1383607266489/1383607344939 CNF 2023: Canadian Nutrient File (CNF). Ottawa (ON): Food and Nutrition, Health Canada. [Accessed 2024 January 12]. Available from: https://www.canada.ca/en/health-canada/services/food-nutrition/healthy-eating/nutrient-data/canadian-nutrient-file-about-us.html FCC 2023: Food Chemicals Codex. 12th edition. Rockville (MD): The United States Pharmacopeial Convention; 2023. 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 2024 January 12]. Available from: https://nap.nationalacademies.org/catalog/10490/dietary-reference-intakes-for-energy-carbohydrate-fiber-fat-fatty-acids-cholesterol-protein-and-amino-acids ITIS 2024: Integrated Taxonomic Information System. Canadian Biodiversity Information Facility. Ottawa (ON): Government of Canada. [Accessed 2024 January 12]. Available from: https://www.itis.gov/ Jung H, Peregrina AA, Rodriguez JM, Moreno-Esparza R. The influence of coffee with milk and tea with milk on the bioavailability of tetracycline. Biopharmaceutics & Drug Disposition 1997;18(5):459-463. Micke P, Beeh KM, Buhl R. Effects of long-term supplementation with whey proteins on plasma glutathione levels of HIV-infected patients. European Journal of Nutrition 2002;41(1):12-18. Potier M, Tomé D. Comparison of digestibility and quality of intact proteins with their respective hydrolysates. Journal of AOAC International 2008;91(4):1002-1005. Shils ME, Olson JA, Shike M, Ross AC, editors. Modern Nutrition in Health and Disease, 10th edition. Philadelphia (PA): Lippincott Williams and Wilkins; 2006. Sweetman SC, editeur. Martindale : The Complete Drug Reference, 37th edition. London (UK) : Pharmaceutical Press; 2011. US FDA 2024: US Food & Drug Administration. Substances added to food. Department of Health and Human Services. [Accessed 2024 January 12]. Available from: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FoodSubstances Wal JM. Cow's milk proteins/allergens. Annals of Allergy Asthma & Immunology 2002;89(6 Suppl 1):3-10. References Reviewed Bégin F, Santizo MC, Peerson JM, Torún B, Brown KH. Effects of bovine serum concentrate, with or without supplemental micronutrients, on the growth, morbidity, and micronutrient status of young children in a low-income, peri-urban Guatemalan community. European Journal of Clinical Nutrition 2008;62(1):39-50. Casswall TH, Sarker SA, Faruque SM, Weintraub A, Albert MJ, Fuchs GJ, Alam NH, Dahlström AK, Link H, Brüssow H, Hammarström L. Treatment of enterotoxigenic and enteropathogenic Escherichia coli-induced diarrhoea in children with bovine immunoglobulin milk concentrate from hyperimmunized cows: a double-blind, placebo-controlled, clinical trial. Scandinavian Journal of Gastroenterology 2000;35(7):711-8. Cribb PJ, Williams AD, Stathis CG, Carey MF, Hayes A. Effects of whey isolate, creatine, and resistance training on muscle hypertrophy Medicine and Science in Sports and Exercise 2007;39(2):298-307. CTFA 2008: Gottschalck TE, Bailey JE, editors. International Cosmetic Ingredient Dictionary and Handbook. 12th edition. Washington (DC): The Cosmetic, Toiletry and Fragrance Association; 2008. Eisenstein J, Roberts SB, Dallal G, Saltzman E. High-protein weight-loss diets: are they safe and do they work? A review of the experimental and epidemiologic data. Nutrition Reviews 2002;60(7 Pt 1):189-200. Fonteh FA, Grandison AS, Lewis MJ. Variations of lactoperoxidase activity and thiocyanate content in cows' and goats' milk throughout lactation. Journal of Dairy Research 2002;69(3):401- 9. Krissansen GW. Emerging health properties of whey proteins and their clinical implications. Journal of the American College of Nutrition 2007;26(6):713S-23S. Review. Lands LC, Iskandar M, Beaudoin N, Meehan B, Dauletbaev N, Berthiuame Y. Dietary supplementation with pressurized whey in patients with cystic fibrosis. Journal of Medicinal Food 2010;13(1):77-82. Lothian JB, Grey V, Lands LC. Effect of whey protein to modulate immune response in children with atopic asthma. International Journal of Food Sciences and Nutrition 2006;57(3-4):204-11. Marshall K. Therapeutic Applications of Whey Protein. Alternative Medicine Review 2004;9(2):136-56. (Review). Moreno YF, Sgarbieri VC, da Silva MN, Toro AA, Vilela MM. Features of whey protein concentrate supplementation in children with rapidly progressive HIV

infection. Journal of Tropical Pediatrics 2006 Feb;52(1):34-8. Pal S, Ellis V, Dhaliwal S. Effects of whey protein isolate on body composition, lipids, insulin and glucose in overweight and obese individuals. British Journal of Nutrition 2010; 9:1-8. Poortmans JR, Dellalieux O. Do regular high protein diets have potential health risks on kidney function in athletes?International Journal of Sport Nutrition and Exercise Metabolism 2000;10(1):28-38. Scherze I, Muschiolik G. Effects of various whey protein hydrolysates on the emulsifying and surface properties of hydrolysed lecithin. Colloids and Surfaces B: Biointerfaces 2001;21(1- 3):107-117. Séverin S, Wenshui X. Milk biologically active components as nutraceuticals: review. Critical Review in Food Science and Nutrition 2005;45(7-8):645-56. Tarnopolsky MA, MacDougall JD, Atkinson SA. Influence of protein intake and training status on nitrogen balance and lean body mass. Journal of Applied Physiology 1988;64(1):187-93. Williams M. Dietary Supplements and Sports Performance: Amino Acids. Journal of the International Society of Sports Nutrition 2005; 2(2):63-67. Wright BJ, Zevchak SE, Wright JM, Drake MA. The impact of agglomeration and storage on flavor and flavor stability of whey protein concentrate 80% and whey protein isolate. Journal of Food Science 2009;74(1):S17-29. Report a problem on this page Date modified: 2019-03-01

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.

DOSE(S)

In order to have a use for a particular mineral, the medicinal ingredient must list the respective mineral as potency on the PLA form and label.

RISK INFORMATION

Caution(s) and warning(s) All products Contains milk by-products (CFIA 2022; Wal 2002).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Products providing more than 30 g protein, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a liver or kidney disorder (Shils et al. 2006; Bell 2000). Contraindication(s) Products providing 100 mg or more potassium, per day Do not use if you are taking other potassium-containing salt-substitutes or supplements (Sweetman 2011). Known adverse reaction(s) Products providing more than 30 g protein, per day When using this product you may experience gastrointestinal discomfort/disturbance(s) (Micke et al. 2002).

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.Whey proteins, especially powders meant to be mixed with a liquid, often require lecithin to act as a dispersing/emulsifying agent. If present, lecithin must be added as a non-medicinal ingredient.

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 the NHPID.The medicinal ingredient proper name should be determined by the potency of whey protein on a dry weight basis as published in the Food and Chemical Codex (FCC 2023).

REFERENCES

1For isolates, 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 material(s)	Part(s)		
Whey protein isolate1	Whey protein isolate	Bos taurusCapra hircus	Milk
Whey protein concentrate	Whey protein concentrate		
Reduced lactose wheyWhey, reduced lactose	Reduced lactose wheyWhey, reduced lactose		
Reduced minerals wheyWhey, reduced minerals	Reduced minerals wheyWhey, reduced minerals		
Whey	Whey		
Whey protein hydrolysate	Whey protein hydrolysate		

Minerals1	Minimum dose (mg/day)	Maximum dose (mg/day)
Calcium	65	1,500
Magnesium	20	500
Phosphorus	62	2,000
Potassium	100	779
Zinc	0.7	50