Health Canada Santé Canada

NATURAL HEALTH PRODUCT

WHEY PRODUCTS

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 ingredients.

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 April 22, 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)
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: FCC 8, INCI 2012; Common names: FCC 8, INCI 2012; Source information: ITIS 2011.

[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)

- Source of (all) essential amino acids (i.e. histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine) for the maintenance of good health (CNF 2010; Potier and Tomé 2008).
- Source of branched chain amino acids for the maintenance of good health (CNF 2010; Potier and Tomé 2008).
- Source of (essential) amino acids involved in muscle protein synthesis (CNF 2010; IOM 2005).
- (Excellent) Source of protein for the maintenance of good health (CFIA 2012).
- (Excellent) Source of protein which helps build and repair body tissues (CFIA 2012).
- (Excellent) Source of protein which helps build antibodies (CFIA 2012).

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

- Source of (all) essential amino acids (i.e. histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine) and branched chain amino acids for the maintenance of good health (CNF 2010; Potier and Tomé 2008).
- (Excellent) Source of protein which helps build and/or repair body tissues and build antibodies (CFIA 2012).

The following claims are acceptable in addition to the source of protein/amino acids claims above. They should not be the only claims made for a Whey product.

Additional Claims (optional)

- Source of the mineral(s) XXX (e.g. calcium, magnesium, phosphorus and/or zinc) for the maintenance of good health (CNF 2010).
- Source of potassium for the maintenance of good health (IOM 2005).

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 Product License Application form and label.

Source of protein

2.6-90 grams of protein per day (CFIA 2012)

Excellent source of protein

16-90 grams of protein per day (CFIA 2012)

Source of amino acids/branched chain amino acids

3-90 grams of protein per day (CFIA 2012)

Source of mineral/potassium

Not to exceed 90 grams of protein per day (CFIA 2012)
and
Table 2. Dose requirements for minerals and potassium levels in whey

Minerals	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

Notes

- The use "*Source of the mineral xxx or source of potassium"* is only acceptable if indicated mineral or potassium is present at dosages at or above the minimum daily dose and not more than the maximum total daily dose as seen in Table 2 above.
- In order to have a use for a particular mineral, the ingredient must list the respective mineral as potency on the Product Licence Application form and label.
- Dose ranges for minerals are based on the NNHPD Multivitamin and Mineral Supplements Monograph.
- Dose ranges for potassium are based on IOM 2005.

Direction(s) for use

Take a few hours before or after taking other medications or natural health products (Martindale 2009; Jung et al. 1997).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

- This product contains milk by-products (CFIA 2011; Wal 2002).
- Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

Products providing more than 30 g protein per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have liver or kidney disease (Shils et al. 2006; Bell 2000).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Products providing more than 30 g protein per day

Some people 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* (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.

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