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

March 25, 2019

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

Table 1. Proper name(s), Common name(s), Source material(s)

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whey protein isolate</td>
<td>Whey protein isolate</td>
<td></td>
</tr>
<tr>
<td>Whey protein concentrate</td>
<td>Whey protein concentrate</td>
<td></td>
</tr>
<tr>
<td>Reduced lactose whey</td>
<td>Reduced lactose whey</td>
<td></td>
</tr>
<tr>
<td>Whey, Reduced Lactose</td>
<td>Whey, Reduced Lactose</td>
<td></td>
</tr>
<tr>
<td>Reduced minerals whey</td>
<td>Reduced minerals whey</td>
<td></td>
</tr>
<tr>
<td>Whey, Reduced Minerals</td>
<td>Whey, Reduced Minerals</td>
<td></td>
</tr>
<tr>
<td>Whey</td>
<td>Whey</td>
<td></td>
</tr>
<tr>
<td>Whey protein hydrolysate</td>
<td>Whey protein hydrolysate</td>
<td></td>
</tr>
</tbody>
</table>


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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

**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).
- (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).
- 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).

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).

**Dose(s)**

**Note**

While the potency of protein for each ingredient on a “dry weight basis” is used to determine the correct proper and common name, the potency of protein on an “as is” weight basis is required to be indicated on the Product License Application (PLA) and label for each protein source/ingredient so that the consumer can accurately calculate the protein amounts provided by the ingredient.

**Subpopulation(s)**

Adults 18 years and older

**Quantity(ies)**

*Source of protein*

8-90 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)

Table 2. Dose requirements for minerals and potassium levels in whey if a related use is being made

<table>
<thead>
<tr>
<th>Minerals</th>
<th>Minimum dose (mg/day)</th>
<th>Maximum Dose (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>65</td>
<td>1500</td>
</tr>
<tr>
<td>Magnesium</td>
<td>20</td>
<td>500</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>62</td>
<td>2000</td>
</tr>
<tr>
<td>Potassium</td>
<td>100</td>
<td>779</td>
</tr>
<tr>
<td>Zinc</td>
<td>0.7</td>
<td>50</td>
</tr>
</tbody>
</table>

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 (Martindale 2009; Jung et al. 1997).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)
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 are pregnant or breastfeeding or if you have liver or kidney disease (Shils et al. 2006; Bell 2000).

Contraindication(s)

All products

Do not use this product if you have a milk allergy (CFIA 2011; Wal 2002).

Known adverse reaction(s)

Products providing more than 30 g protein per day

This product may cause mild gastrointestinal disturbances (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

No statement required.

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.
- In addition, 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 8) (refer to table 3):
Table 3. Proper names of whey ingredients as determined by the potency of whey protein on a dry weight basis

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Potency of whey protein(^1) (dry weight basis(^2)) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whey protein isolate</td>
<td>≥ 90</td>
</tr>
<tr>
<td>Whey protein concentrate</td>
<td>25-89.9</td>
</tr>
<tr>
<td>Whey, Reduced Lactose(^3)</td>
<td>16-24</td>
</tr>
<tr>
<td>Reduced lactose whey</td>
<td></td>
</tr>
<tr>
<td>Whey, Reduced Minerals(^4)</td>
<td>10-24</td>
</tr>
<tr>
<td>Reduced minerals whey</td>
<td></td>
</tr>
<tr>
<td>Whey</td>
<td>10-15</td>
</tr>
<tr>
<td>Whey protein hydrolysate(^5)</td>
<td>≥ 10(^6)</td>
</tr>
</tbody>
</table>

\(^1\) Potencies of whey protein on a "dry weight basis" are based on values derived from FCC 8.
\(^2\) Chemical and physical components are typically reported on an “as is” (wet) weight basis or dry (0% moisture) weight basis. A wet weight basis result is the percentage of the component of interest out of the entire sample including moisture. A dry weight basis result is the percentage of the component out of the entire sample neglecting moisture.
\(^3\) As per FCC 8, reduced lactose whey should not contain more than 60% lactose (calculated on a dry weight basis).
\(^4\) As per FCC 8, reduced minerals whey should not contain more than 7% ash (calculated on a dry weight basis).
\(^5\) Refers to partially hydrolyzed proteins composed of peptides and polypeptides resulting from the partial or incomplete hydrolysis of peptide bonds present in edible whey protein catalyzed by heat, food-grade proteolytic enzymes, and/or suitable food-grade acids. Their degree of hydrolysis typically ranges from 3% to 85% on the basis of peptide bond cleavage (FCC 8).
\(^6\) Minimum quantity of protein is based upon a minimum of 10% (dry weight basis) of protein found in dry whey.

References cited


Cribb PJ, Williams AD, Stathis CG, Carey MF, Hayes A. Effects of whey isolate, creatine, and resistance training on muscle hypertrophy Medicine & Science in Sports & Exercise


References reviewed


