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 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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date August 22, 2013

Proper name(s), Common name(s)

Table 1 Proper and common name of whey ingredients as determined by the potency of whey protein on a dry weight basis

<table>
<thead>
<tr>
<th>Proper name(s)¹</th>
<th>Common name(s)²</th>
<th>Potency of whey protein³ (dry weight basis⁴) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whey protein isolate</td>
<td>Whey protein isolate</td>
<td>≥ 90</td>
</tr>
<tr>
<td>Whey protein concentrate</td>
<td>Whey protein concentrate</td>
<td>25-89.9</td>
</tr>
<tr>
<td>Whey, Reduced Lactose³ Reduced lactose whey</td>
<td>Whey, Reduced Lactose Reduced lactose whey</td>
<td>16-24</td>
</tr>
<tr>
<td>Whey, Reduced Minerals⁶ Reduced minerals whey</td>
<td>Whey, Reduced Minerals Reduced minerals whey</td>
<td>10-24</td>
</tr>
<tr>
<td>Whey</td>
<td>Whey</td>
<td>10-15</td>
</tr>
<tr>
<td>Whey protein hydrolysate⁷</td>
<td>Whey protein hydrolysate</td>
<td>≥ 10⁸</td>
</tr>
</tbody>
</table>

¹ At least one of the following references was consulted per proper name: FCC 8, INCI 2012.
² At least one of the following references was consulted per common name: FCC 8, INCI 2012.
³ Potencies of whey protein on a “dry weight basis” are based on values derived from FCC 8.
⁴ 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. Please see Appendix 1 for further details.
⁵ As per FCC 8, reduced lactose whey should not contain more than 60% lactose (calculated on a dry weight basis)
⁶ As per FCC 8, reduced minerals whey should not contain more than 7% ash (calculated on a dry weight basis)
⁷ 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).
Minimum quantity of protein is based upon a minimum of 10% (dry weight basis) of protein found in dry whey.

Source material(s)

- *Bos taurus/cow milk* (ITIS 2011)
- *Capra hircus/goat milk* (ITIS 2011)

Route(s) of administration

Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)

Statement(s) to the effect of

- 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).

Dose(s)

Statement(s) to the effect of

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. Please see Appendix 1 for the determination of protein content on an “as is” and “dry” weight basis.

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

The potency of whey on a “as is” weight basis is required to be indicated on the Product License Application (PLA) form and label (see notes above).

Source of protein

8-90 g protein per day (CFIA 2012)

Excellent source of protein

16-90 g protein per day (CFIA 2012)

Source of amino acids/branched chain amino acids

3-90 g protein per day (CFIA 2012)

Source of mineral/potassium

Up to 90 g protein per day (CFIA 2012)

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

<table>
<thead>
<tr>
<th>Mineral</th>
<th>Minimum daily dose (mg)</th>
<th>Maximum Daily Dose (mg)</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 or purpose source of the mineral xxx or source of potassium is only acceptable if the 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 or purpose 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 NHPD Multivitamin and Mineral Supplements Monograph.

Dose ranges for potassium are based on IOM 2005.

**Directions for use**

Take a few hours before or after taking other medications (Martindale 2009; ASHP 2005; Jung et al. 1997).

**Duration of use**

No statement required.

**Risk information**

Statement(s) to the effect of

**Caution(s) and warning(s)**

Products providing > 30 g protein per day:
- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- If you have liver or kidney disease, consult a health care practitioner prior to use (Shils et al. 2006; Bell 2000).

**Contraindication(s)**

If you have a milk allergy, do not use this product (CFIA 2011; Wal 2002).

**Known adverse reaction(s)**

Products providing > 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 NHPD *[Natural Health Products Ingredients Database](http://www.nhpidal.com)* (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**

Statement(s) to the effect of

No statement required.
Specifications

- The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID). In addition, the medicinal ingredient may comply with the specifications outlined in the following Whey monographs published in the Food and Chemical Codex (FCC 8):
  - Whey
  - Whey Protein Concentrate
  - Whey Protein Isolate
  - Whey, Reduced Lactose
  - Whey, Reduced Minerals

References cited


References reviewed


Appendix 1  Definition of “as is” and “dry” weight basis

Chemical and physical components are typically reported on an “as is” (wet) 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. For example:

A whey protein sample is analyzed to contain 87% protein, 4% moisture, and 9% other components as it sits in a sample container. The protein content is 87% on a wet weight basis (“as is”). Since 4% of the sample is water, 96% is “dry material”. Thus 87 parts protein divided by 96 parts of dry material gives a protein content of 90.6% on a dry weight basis.

Example 1:  Protein on an “as is” (wet) weight basis: 90%
Moisture content: 6%
Dry material: 94%

The “dry” percentage protein = 90/(100-6) = 95.7%

The name of the ingredient is “Whey protein isolate” (assuming un-hydrolysed protein) and the % protein listed as a potency on the PLA form and label is 90%

Example 2:  Protein on a dry weight basis: 90%
Moisture content: 5%
Dry material: 95%

The “as is” percentage protein = 90 x 95/100 = 85.5%

The name of the ingredient is “Whey protein isolate” (assuming un-hydrolysed protein) and the % protein listed as a potency on the Product License Application (PLA) form and label is 85.5%.