Dried Dairy Ingredients

Types of milk, whey and permeate ◇ Summary of dried dairy ingredients ◇ Dairy ingredients from milk ◇ Dairy ingredients from whey
Introduction

The Dried Dairy Ingredient Handbook is designed to be an easy to use, quick source of information on the wide range of ingredients that can be made from milk and whey. The Handbook is intended only as a guide to dairy ingredients. Product manufacturing methods, composition and specifications will vary between producers. The guide describes what is typical for products.

Some ingredients can be made from either milk or whey but they have been included in the section under the starting material most typically used.

Information on products is given in several different formats reflecting the varied ways information on dry dairy products is conveyed. Graphs of product composition are on a total solids basis thereby allowing a quick comparison of components. Tables of product composition include moisture thereby reflecting what a customer would typically see for a bag of dry product. The table of typical composition and characteristics gives composition information in a format similar to the product composition table but protein is given on a dry basis.

Regulations for US dairy products often are distributed throughout several agencies. It may be necessary to consult several sources to obtain complete information on regulations and standards for a given product.

Standards and specifications also may vary between government agencies and trade groups. It is important to check for regulations governing your particular product as well as for any changes in regulations/standards.

I would like to thank the people in industry and at CDR that contributed to and reviewed the document. Their assistance was invaluable. I would like to give special thanks to Tim Hogensen for all of his time and patience in producing this handbook.

Karen Smith
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Types of Milk, Whey and Permeate

Milk
Whole
Skim
Buttermilk (from butter manufacture)

Whey
Resulting from:
Cheese manufacture
  - Sweet
  - Acid
  - Salty
Casein production
  - Sweet
  - Acid
Greek yogurt production
  - Acid

Permeate
Resulting from:
Milk
Cheese manufacture
  - Sweet whey
  - Acid whey
Casein manufacture
  - Sweet whey
  - Acid whey

General composition of milk, whey and permeate

<table>
<thead>
<tr>
<th>Component</th>
<th>Milk</th>
<th>Sweet whey</th>
<th>Whey permeate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total solids</td>
<td>12.5</td>
<td>6.5</td>
<td>5.5</td>
</tr>
<tr>
<td>Protein</td>
<td>3.5</td>
<td>0.8</td>
<td>&lt; 0.1</td>
</tr>
<tr>
<td>Lactose</td>
<td>4.8</td>
<td>4.9</td>
<td>4.9</td>
</tr>
<tr>
<td>Ash</td>
<td>0.7</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Fat</td>
<td>3.5</td>
<td>0.3</td>
<td>0.0</td>
</tr>
</tbody>
</table>
Dried Dairy Ingredients

Milk based
- Milk powder
  - Nonfat dry milk (NFDM, NDM)
    - Low heat
    - Medium heat
    - High heat
  - Whole milk
  - Buttermilk
- Colostrum
  - Skim
  - Whole
- Casein
  - Acid
  - Rennet
- Caseinate
  - Potassium
  - Calcium
  - Sodium
- Co-precipitate
  - Acid
    - Medium calcium
    - High calcium
- Milk protein concentrate (MPC)
  - 42 to 85
- Milk protein isolate (MPI)
- Reduced calcium milk protein concentrate
- Permeate (milk)
- Micellar casein
- Native whey protein

Whey based
- Whey
  - Sweet
  - Acid
- Demineralized (reduced minerals) whey
  - 25 to 90%
- Reduced lactose whey
- Lactose hydrolyzed whey
- Protein hydrolyzed whey
- Lactalbumin
- Whey protein concentrate (WPC)
  - 34 to 80
- Whey protein isolate (WPI)
- Heat stable whey protein concentrate
- Whey protein phospholipid concentrate (WPPC)
- Alpha-lactalbumin enriched whey protein concentrate
- Individual proteins
  - Lactoferrin
  - Lactoperoxidase
  - Glycomacropeptide (GMP)
- Permeate (whey)
- Galacto-oligosaccharides (GOS)
- Lactose
  - Food
  - Pharmaceutical
- Dairy minerals
Milk Powder

Milk powders are skim milk, whole milk or buttermilk with only water removed. All of the original constituents except water are present in their original ratios.

Note: The terms nonfat dry milk and skim milk powder are often used interchangeably but they are defined by two different sets of regulations and authorities. Nonfat dry milk is defined by FDA/USDA and skim milk powder is defined by Codex Allimentarius. Dry whole milk and whole milk powder also are used interchangeably but again are defined by two different sets of regulations and authorities. FDA/USDA defines and regulates dry whole milk while Codex Allimentarius defines and regulates whole milk powder.

Heat treatment of nonfat dry milk

Nonfat dry milk (NFDM, NDM), also known as skim milk powder (SMP), may receive a heat treatment in addition to pasteurization.

The heat treatment alters the functional properties of NFDM. Whey protein nitrogen index (WPNI) is a measure of the amount of heat treatment the powder has received. Whey proteins are denatured or altered by heat. The test measures the amount of undenatured whey protein present in the powder. Lower levels of undenatured whey protein in the powder indicate exposure to higher temperatures.

WPNI does not indicate the heat stability of the powder.

Low heat powder will have < 25% of the whey protein denatured while > 81% of the whey proteins are denatured in high heat powder.

Type of dryer used

Milk powder functionality is affected by the type of dryer used.

Majority of milk powder is produced by spray drying which is a less severe process than roller drying.

Roller drying milk powder is relatively uncommon because of the amount of protein denaturation that results. Roller dried product will have a flaked appearance, browner color and more cooked flavor compared to sprayed dried powder.

Final form of the powder

Agglomeration is used to increase particle size and is a step in the instantizing process.

Instantizing improves the ability of powder to disperse and dissolve quickly. Lecithin may be added to whole milk or buttermilk powder to improve the ability of higher fat products to go into solution.

Agglomeration and instantizing do not improve powder solubility. Rather they increase the rate of powder dispersing and dissolving. Powder that is insoluble will not be made soluble if agglomerated or instantized.

Agglomerated/instantized powder will have a shorter shelf life as compared to ordinary powder because of the additional heat treatment used during manufacture.
### Types
- Nonfat
- Whole
- Buttermilk

### Grades
- Extra grade
- Standard grade
- Grade not assignable

### Pre-heat treatments (nonfat)
- Low heat
- Medium heat
- High heat

### Dryer used
- Roller
- Spray

### Final form
- Ordinary (non-agglomerated, non-instant)
- Agglomerated
- Instantized

---

### Regulations
- **Nonfat dry milk**
  - 21 CFR 131.125
    - United States Standards for Grades of Nonfat Dry Milk (Spray Process)
      - USDA, AMS - Dairy Division, February 2, 2001
  - United States Standards for Grades of Nonfat Dry Milk (Roller Process)
    - USDA, AMS - Dairy Division, May 18, 1984
  - United States Standards for Grades of Instant Nonfat Dry Milk
    - USDA, AMS - Dairy Division, February 2, 2001

- **Skim milk powder**
  - Codex Stan 207-1999

- **Dry whole milk**
  - 21 CFR 101.4 (b)(4)
    - United States Standards for Grades of Dry Whole Milk
      - USDA, AMS - Dairy Division, April 13, 2001

- **Whole milk powder**
  - Codex Stan 207-1999

- **Buttermilk**
  - 21 CFR 101.4 (b)(6)
    - United States Standards for Grades of Dry Buttermilk and Dry Buttermilk Product
      - USDA, AMS - Dairy Division, February 2, 2001
Milk Powder Definitions
(summarized from Code of Federal Regulations)

Nonfat dry milk (NFDM, NDM) is the product obtained by removal of water only from pasteurized skim milk. It contains not more than 5% by weight moisture, and not more than 1.5% by weight milk fat unless otherwise indicated. Product also may be known as skim milk powder (SMP).

Dry whole milk (DWM) is the product resulting from the removal of water from pasteurized milk and contains by weight not less than 26%, but less than 40% milk fat and not more than 5% by weight of moisture. It contains lactose, milk proteins, milk fat and milk minerals in the same proportions as the milk from which it was made.

Dry buttermilk (DBM) is obtained by removing water from liquid buttermilk derived from the churning of butter. It shall contain not less than 4.5% milkfat and not more than 5% moisture. It shall have a protein content of not less than 30%.

The phospholipid and total lipid content of dried buttermilk is higher than NFDM. It may not contain or be derived from, skim milk powder, dry whey or products other than buttermilk, and contains no added preservative, neutralizing agent or other chemicals.

Dry buttermilk product (DBP) shall contain not less than 4.5% milkfat and not more than 5% moisture. Dry buttermilk product contains less than 30% protein and the label should specify the minimum protein content.

Additional ADPI Definitions

Instant nonfat dry milk (INDM) is nonfat dry milk which has been produced in a manner to substantially improve its dispersing and reconstitution characteristics. INDM for human consumption complies with all provisions of the U.S. Federal Food, Drug, and Cosmetic Act.

Reduced Fat Milk Powder is the product resulting from the partial removal of fat and water from pasteurized milk. The fat and/or protein content of the milk may have been adjusted, only to comply with the compositional requirements below, by the addition and/or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of the milk being adjusted.

### General composition of milk powders

<table>
<thead>
<tr>
<th>Component</th>
<th>Skim</th>
<th>Whole</th>
<th>Buttermilk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total protein</td>
<td>36.0</td>
<td>26.0</td>
<td>34.0</td>
</tr>
<tr>
<td>Lactose</td>
<td>51.0</td>
<td>37.0</td>
<td>48.0</td>
</tr>
<tr>
<td>Ash</td>
<td>8.2</td>
<td>6.0</td>
<td>8.5</td>
</tr>
<tr>
<td>Fat</td>
<td>0.8</td>
<td>27.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Moisture</td>
<td>4.0</td>
<td>4.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>
### Classification of nonfat dry milk*

<table>
<thead>
<tr>
<th>Category</th>
<th>Typical processing treatment</th>
<th>WPNI (mg/g undenatured whey protein)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Temp (°C)</td>
<td>Time (minutes)</td>
</tr>
<tr>
<td>Low-heat</td>
<td>70</td>
<td>158</td>
</tr>
<tr>
<td>Medium-heat</td>
<td>70 - 78</td>
<td>158 - 172</td>
</tr>
<tr>
<td>High-heat</td>
<td>88</td>
<td>190</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of nonfat dry milk (spray process)

### Specifications for US Grades of nonfat dry milk (spray)*

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>1.25%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Moisture</td>
<td>4.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.15%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>1.2 ml**</td>
<td>2.0 ml***</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>15.0 mg</td>
<td>22.5 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>10,000/g</td>
<td>75,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>10/g</td>
<td>10/g</td>
</tr>
</tbody>
</table>

** Except high heat not greater than 2.0
*** Except high heat not greater than 2.5

* USDA Dairy Standards for grades of nonfat dry milk (spray process)

### Specifications for US Grades of dry whole milk (spray)*

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>&gt;26% but &lt; 40%</td>
<td>&gt;26% but &lt; 40%</td>
</tr>
<tr>
<td>Moisture</td>
<td>4.5%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.15%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>1.0 ml</td>
<td>1.5 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>15.0 mg</td>
<td>22.5 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>10,000/g</td>
<td>50,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>10/g</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of dry whole milk
** As determined by weight of moisture on a milk solids-not-fat basis

### Specifications for US Grades of dry whole milk (roller)*

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>&gt;26% but &lt; 40%</td>
<td>&gt;26% but &lt; 40%</td>
</tr>
<tr>
<td>Moisture</td>
<td>4.5%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.15%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>15.0 ml</td>
<td>15.0 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>22.5 mg</td>
<td>32.5 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>10,000/g</td>
<td>50,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>10/g</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of dry whole milk
** As determined by weight of moisture on a milk solids-not-fat basis
**Specifications for US Grades of dry buttermilk (spray)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
<td>not greater than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>4.5%</td>
<td>-</td>
</tr>
<tr>
<td>Protein</td>
<td>30.0%</td>
<td>-</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>4.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.10%</td>
<td>0.18%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>-</td>
<td>1.25 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>-</td>
<td>15.0 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>-</td>
<td>20,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>-</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of dry buttermilk and dry buttermilk product

**Specifications for US Grades of dry buttermilk (roller)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
<td>not greater than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>4.5%</td>
<td>-</td>
</tr>
<tr>
<td>Protein</td>
<td>30.0%</td>
<td>-</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>4.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.10%</td>
<td>0.18%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>-</td>
<td>15.0 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>-</td>
<td>22.5 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>-</td>
<td>20,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>-</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of dry buttermilk and dry buttermilk product

**Specifications for US Grades of dry buttermilk product (spray)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
<td>not greater than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>4.5%</td>
<td>-</td>
</tr>
<tr>
<td>Protein</td>
<td>-</td>
<td>30.0%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>4.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.10%</td>
<td>0.18%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>-</td>
<td>1.25 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>-</td>
<td>15.0 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>-</td>
<td>20,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>-</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of dry buttermilk and dry buttermilk product

**Specifications for US Grades of dry buttermilk product (roller)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
<td>not greater than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>4.5%</td>
<td>-</td>
</tr>
<tr>
<td>Protein</td>
<td>-</td>
<td>30.0%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>4.0%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.10%</td>
<td>0.18%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>-</td>
<td>15.0 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>-</td>
<td>22.5 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>-</td>
<td>20,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>-</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of dry buttermilk and dry buttermilk product
Skimmed Milk Powder (SMP)

Skimmed milk powder is defined by Codex Alimentarius. The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Codex definitions and specifications for SMP differ from US standards for NFDM. Whole milk powder and partly skimmed milk powder also are defined by Codex.

An important difference between Codex and US standards is the adjustment of protein levels. Codex allows the protein content of milk powder to be adjusted through the addition of milk retentate, milk permeate or lactose. The protein content of SMP typically is lower than the protein content of NFDM.

**Codex specifications for milk powders***

<table>
<thead>
<tr>
<th>Component</th>
<th>Skimmed</th>
<th>Partly skimmed</th>
<th>Whole</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>&lt; 1.5%</td>
<td>1.5% but &lt; 26%</td>
<td>≥ 26% but &lt; 42%</td>
</tr>
<tr>
<td>Protein**</td>
<td>&gt; 34%</td>
<td>&gt; 34%</td>
<td>&gt; 34%</td>
</tr>
<tr>
<td>Moisture</td>
<td>5%</td>
<td>5%</td>
<td>not greater than 5%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.18%</td>
<td>0.18%</td>
<td>0.18%</td>
</tr>
<tr>
<td>Solubility index</td>
<td>1.0 ml</td>
<td>1.0 ml</td>
<td>1.0 ml</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>15.0 mg</td>
<td>15.0 mg</td>
<td>15.0 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>10,000/g</td>
<td>50,000/g</td>
<td>10,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>10/g</td>
<td>10/g</td>
<td>10/g</td>
</tr>
</tbody>
</table>

* Codex Stan 207-1999
** Milk protein as determined on a milk solids-not-fat basis
### Typical composition and characteristics

#### Nonfat dry milk

- **Typical composition**
  - Protein (db): 37.3%
  - Moisture: 3.5%
  - Lactose: 51%
  - Fat: 1%
  - Ash: 8.5%

- **Storage**
  - <27 C, <65% rh
  - 12–18 months
  - 6–12 months (instant)

#### Whole milk

- **Typical composition**
  - Protein (db): 26.8%
  - Moisture: 3%
  - Lactose: 38%
  - Fat: 27%
  - Ash: 6%

- **Storage**
  - <27 C, <65% rh
  - 6–9 months
  - Shelf life very dependent on storage conditions

#### Buttermilk

- **Typical composition**
  - Protein (db): 34.4%
  - Moisture: 4%
  - Lactose: 48%
  - Fat: 6.5%
  - Ash: 8.5%

- **Storage**
  - <27 C, <65% rh
  - 6–9 months
  - Shelf life very dependent on storage conditions

#### Characteristics

- **Nonfat dry milk**
  - Color: white to light cream
  - Flavor: clean, dairy
  - Titratable acidity: <0.14%
  - Solubility index:
    - Instant: 1.0 ml
    - Low heat spray: 1.2 ml
    - High heat spray: 2.0 ml
    - Roller dried: 15.0 ml
  - Scorch particle content:
    - Spray dried: <15 mg
    - Roller dried: <22.5 mg

- **Whole milk**
  - Color: white to light cream
  - Flavor: clean, dairy
  - Titratable acidity: <0.15%
  - Solubility index:
    - Spray dried: 1.25 ml
    - Roller dried: 15.0 ml
  - Scorch particle content:
    - Spray dried: <15 mg
    - Roller dried: <22.5 mg

- **Buttermilk**
  - Color: uniform cream to dark
  - Flavor: clean, dairy
  - Titratable acidity: 0.10 – 0.18%
  - Solubility index:
    - Spray dried: 1.25 ml
    - Roller dried: 15.0 ml
  - Scorch particle content:
    - Spray dried: <15 mg
    - Roller dried: <22.5 mg

---

**Raw Text**

Dried Dairy Ingredients
Cream

Dry cream products have fat contents greater than whole milk powders. Drying high fat products can be difficult and may require the addition of other ingredients to keep the fat globules in a stable emulsion. The fat typically must be emulsified or encapsulated, often with milk proteins, before cream can be dried successfully. If the fat is not encapsulated properly the resulting powder will stick to dryer surfaces and powder handling equipment.

The information provided here is a general outline given the process for drying cream can vary significantly depending on the end use of the powder.

Cream powder results from the removal of water from pasteurized cream. The fat and/or protein content of the cream may be adjusted but only of needed to comply with the compositional requirements of the CFR. Milk constituents may be added or removed as long as the whey protein to casein ratio of the cream is not altered.

Dry Cream Definition

Dry cream is the product obtained by removal of water only from pasteurized milk or cream or a mixture thereof, which may have been homogenized. Alternatively, dry cream may be made by blending dry milk with dry cream provided that the resulting product is equivalent in composition to dry cream made by the water removal method. Dry cream contains not less than 40% but less than 75% by weight milkfat on an as is basis and not more than 5% by weight moisture on a milk solids not fat basis.

Optional ingredients include emulsifiers, stabilizers, anticaking agents, antioxidants, nutritive carbohydrate sweeteners and flavoring agents (with and without coloring)

Dry Cream Definition

(summarized from Codex)

Cream powder can be obtained by the partial removal of water from cream. The fat and/or protein content of the cream may have been adjusted, only to comply with the compositional requirements. Addition and/or withdrawal of milk constituents must be done in such a way as not to alter the whey protein casein ratio of the milk.

Codex permits the use of the following products for standardization of dry cream:
- Milk retentate
- Milk permeate
- Lactose

ADPI Dry Cream Definition

Cream powder is the product resulting from the partial removal of water from pasteurized cream. The fat and/or protein content of the cream may have been adjusted, only to comply with the compositional requirements below, by the addition and/or withdrawal of milk constituents in such a way as not to alter the whey protein to casein ratio of the cream being adjusted.

Regulations
- 21 CFR 131.149
- Codex Stan 207-1999

ADPI Industry Standard
**Codex specifications for dry cream**

<table>
<thead>
<tr>
<th>Component</th>
<th>Dry Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>42%</td>
</tr>
<tr>
<td>Protein**</td>
<td>34%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
</tr>
</tbody>
</table>

* Codex Stan 207-1999
**Protein in milk-solids-not-fat basis

**CFR specifications for dry cream**

<table>
<thead>
<tr>
<th>Component</th>
<th>Dry Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>40%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
</tr>
</tbody>
</table>

* 21 CFR 131.149

**ADPI industry standard for dry cream**

<table>
<thead>
<tr>
<th>Component</th>
<th>Dry Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>42%</td>
</tr>
<tr>
<td>Protein*</td>
<td>34%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
</tr>
</tbody>
</table>

*Protein in milk-solids-not-fat basis

**General composition of dry cream**

<table>
<thead>
<tr>
<th>Component</th>
<th>Dry cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>na</td>
</tr>
<tr>
<td>Lactose</td>
<td>40 - 75</td>
</tr>
<tr>
<td>Ash</td>
<td>na</td>
</tr>
<tr>
<td>Fat</td>
<td>na</td>
</tr>
<tr>
<td>Moisture</td>
<td>5</td>
</tr>
</tbody>
</table>

**General composition of dry cream**

- **Fat**: 80%
- **Ash**: 20%
- **Lactose**: 60%
- **Protein**: 42%
- **Protein** (milk-solids-not-fat basis): 34%
- **Moisture**: 5%
Manufacture of Dry Cream

Typical composition and characteristics

**Dry cream**
- **Typical composition**
  - Protein (db) na%
  - Moisture 3%
  - Lactose na%
  - Fat 72%
  - Ash na%
- **Characteristics**
  - Color: light cream
  - Flavor: sweet cream
  - TA <0.18%
- **Storage**
  - <27 C, <70% rh
  - 12 months

*Exact composition depends on manufacturer*

**CFR Product Labeling**
Dry cream (Contains ____% milkfat)

The percent fat is given as the whole number closest to the actual fat content of the product.

**Codex Product Labeling**
Cream powder
**Colostrum**

Colostrum is the milk that comes from cows within 48 hours of giving birth. Colostrum is a concentrated source of biologically active compounds that are needed to promote the health and growth of the calf.

The composition of colostrum is highly variable. The individual cow, breed, nutrition and length of dry period are a few of the factors that influence composition. In general, colostrum contains less lactose and more protein, peptides, non-protein nitrogen, minerals, vitamins and bioactive compounds than regular milk.

Some of the components of colostrum that often are of interest from the standpoint of health and wellness include:

- **Cytokines** - small proteins that are involved in the generation of special types of white blood cells and directing the white blood cells to injury sites.
- **Thymosin** - a hormone that works with the thymus gland to maintain the immune system.
- **Proline-rich peptide** - acts upon the thymus gland to regulate response to injury.
- **Immunoglobulins (IgG, IgM, IgA)** - are a group of proteins known as antibodies that protect against bacteria and viruses.
- **Transfer factors** - small proteins that work in concert with white blood cells to control unwanted bacteria.
- **Lactoferrin** - an iron binding protein that can inhibit the growth of certain bacteria such as E. coli.
- **Transferrin** - another iron binding protein that works with lactoferrin to inhibit growth of certain bacteria.
- **Lysozyme** - an enzyme that can kill certain disease causing bacteria.
- **Lactoperoxidase** - an enzyme similar to lysozyme.
- **Oligosaccharides** - complex carbohydrates that limit the attachment of microorganisms to the intestine.
- **Insulin-like growth factors (IGFs)** - hormones involved in the growth and reproduction of cells.
- **Mineral binding proteins** - examples are lactoferrin and transferrin which can bind minerals such as iron making the iron more readily absorbed by the body.

---

**Skim colostrum powder (ADPI definition)** - is obtained by the partial removal of fat and water from colostrum that comes from cows within 48 hours after giving birth. It contains fat (<6%), proteins, carbohydrates, vitamins and minerals. Skim Colostrum Powder for human consumption complies with all provisions of the U.S. Federal Food, Drug and Cosmetic Act.

**Whole colostrum powder (ADPI definition)** - is obtained by the drying of colostrum that comes from cows within 48 hours after giving birth. It contains fat (>17.5%), proteins, carbohydrates, vitamins and minerals. Whole Colostrum Powder for human consumption complies with all provisions of the U.S. Federal Food, Drug and Cosmetic Act.

**Types**
- Skim colostrum (fat has been removed)
- Whole colostrum (fat has not been removed)

**Regulations**
- US Federal Food, Drug and Cosmetic Act
- ADPI Industry Standard

---

**Colostrum composition**

<table>
<thead>
<tr>
<th>Percentage of total solids (%)</th>
<th>NFDM</th>
<th>Skim colostrum</th>
<th>Whole colostrum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td>100</td>
<td>80</td>
<td>60</td>
</tr>
<tr>
<td>Ash</td>
<td>20</td>
<td>40</td>
<td>80</td>
</tr>
<tr>
<td>Lactose</td>
<td>40</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Protein</td>
<td>20</td>
<td>20</td>
<td>20</td>
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</tbody>
</table>
### General composition of colostrum

<table>
<thead>
<tr>
<th>Component</th>
<th>Colostrum</th>
<th>Skim</th>
<th>Whole</th>
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</thead>
<tbody>
<tr>
<td>Protein</td>
<td>62</td>
<td>50</td>
<td>-</td>
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<tr>
<td>Lactose</td>
<td>22</td>
<td>18</td>
<td>-</td>
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<tr>
<td>Ash</td>
<td>8</td>
<td>6</td>
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<td>Fat</td>
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<td>-</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
<td>4</td>
<td>-</td>
</tr>
</tbody>
</table>

### ADPI industry standard for skim colostrum

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>62</td>
<td>50</td>
<td>-</td>
</tr>
<tr>
<td>Lactose</td>
<td>22</td>
<td>-</td>
<td>35.0</td>
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<tr>
<td>Ash</td>
<td>8</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fat</td>
<td>4</td>
<td>-</td>
<td>6.0</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
<td>-</td>
<td>6.0</td>
</tr>
</tbody>
</table>

### ADPI industry standard for whole colostrum

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>50</td>
<td>40</td>
<td>-</td>
</tr>
<tr>
<td>Lactose</td>
<td>18</td>
<td>-</td>
<td>35.0</td>
</tr>
<tr>
<td>Ash</td>
<td>6</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fat</td>
<td>22</td>
<td>17.5</td>
<td>-</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
<td>-</td>
<td>6.0</td>
</tr>
</tbody>
</table>

### Manufacture of Whole and Skim Colostrum

1. Colostrum
2. Separate
3. Pasteurize
4. Spray dry
5. Water
6. Whole Colostrum
7. Skim Colostrum

### Typical composition and characteristic

Not available
Casein

Casein is the major protein present in milk. Approximately 80% of the protein in milk is casein while whey proteins account for the remaining 20%.

Commercial casein is prepared from pasteurized skim milk. Acid or rennet is used to coagulate the casein. A washing step is included to remove impurities such as lactose and minerals and thereby increase shelf life of the product. The functional properties of the resulting casein will depend on the coagulation method used.

Casein isolated by coagulation is in a not native or non-micellar form and is not soluble. Additional treatments are required to convert the casein into caseinates which are soluble.

Types

- Mineral acids
  - Hydrochloric
  - Sulfuric
  - Orthophosphoric
- Organic acids
  - Lactic
    - Produced by starter culture
    - Addition of lactic acid
  - Acetic
  - Citric
- Rennet

Dryer

- Roller
- Spray

Regulations

- Acid casein
  United States Standards for Grades of Edible Dry Casein (Acid)
  USDA, AMS - Dairy Division, July 20, 1968

- Rennet casein

Casein composition

- Percentage of total solids (%)
- NFDM
  - Fat
  - Ash
  - Lactose
  - Protein
- Rennet casein
- Acid casein
### General composition of casein

<table>
<thead>
<tr>
<th>Component</th>
<th>Rennet</th>
<th>Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>80.5</td>
<td>86.5</td>
</tr>
<tr>
<td>Lactose</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Ash</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Fat</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Moisture</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>pH</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>

### Codex specifications for casein products*

<table>
<thead>
<tr>
<th>Component</th>
<th>Rennet</th>
<th>Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
<td>not greater than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>-</td>
<td>2.0%</td>
</tr>
<tr>
<td>Protein (db)</td>
<td>84.0%</td>
<td>-</td>
</tr>
<tr>
<td>Casein in protein</td>
<td>95.0%</td>
<td>-</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>12.0%</td>
</tr>
<tr>
<td>Lactose**</td>
<td>-</td>
<td>1.0%</td>
</tr>
<tr>
<td>Ash</td>
<td>7.5%</td>
<td>-</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>-</td>
<td>15 mg</td>
</tr>
</tbody>
</table>

** Expressed in anhydrous form

### Specifications for US Grades of acid casein*

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>not less than</td>
</tr>
<tr>
<td>Protein (db)</td>
<td>95%</td>
<td>90%</td>
</tr>
<tr>
<td>Milkfat</td>
<td>1.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Moisture</td>
<td>10%</td>
<td>12%</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>0.20%</td>
<td>0.27%</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>15 mg</td>
<td>22.5 mg</td>
</tr>
<tr>
<td>Bacteria</td>
<td>30,000/g</td>
<td>100,000/g</td>
</tr>
<tr>
<td>Coliforms</td>
<td>none/0.1g</td>
<td>2/0.1g</td>
</tr>
</tbody>
</table>

* USDA Dairy Standards for grades of casein (acid)
Manufacture of Casein

Rennet casein

Lactic acid casein

Mineral acid casein

Pasteurized skim milk

Rennet

30°C

Starter bacteria

23°C

Acid

32°C

Gel forms

Cut gel

60°C
Stir curd

50 - 55°C
Stir curd

45°C
Stir curd

Separate

Whey

Casein aggregates

Water

Wash/centrifuge

Water and impurities

Dry/grind

Rennet Casein

Lactic Acid Casein

Mineral Acid Casein

Typical composition and characteristics

Rennet casein

- Typical composition
  - Protein (db) 90%
  - Moisture 10%
  - Lactose 0.5%
  - Fat 1%
  - Ash 8%
- Characteristics
  - Color: white to cream
  - Flavor: bland
  - pH 7
- Storage
  - <26 C, <65% rh
  - 12 months

Acid casein

- Typical composition
  - Protein (db) 90%
  - Moisture 10%
  - Lactose 0.5%
  - Fat 2%
  - Ash 2.5%
- Characteristics
  - Color: white to cream
  - Flavor: bland
  - pH 4.6
- Storage
  - <26 C, <65% rh
  - 18 months
Caseinate

Acid or rennet casein are insoluble in water but they may be treated with alkali to make a caseinate which is soluble. The exact alkali used will determine the functional properties of the resulting caseinate.

**Types**
- Alkali used
  - Sodium hydroxide or carbonate
  - Potassium hydroxide
  - Calcium hydroxide
  - Ammonium hydroxide
- Dryer used
  - Roller dryer
  - Spray dryer
  - Extruded

**Regulations**

### General composition of caseinate

<table>
<thead>
<tr>
<th>Component</th>
<th>Caseinate type</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Potassium</td>
</tr>
<tr>
<td>Protein</td>
<td>88</td>
</tr>
<tr>
<td>Lactose</td>
<td>0.3</td>
</tr>
<tr>
<td>Ash</td>
<td>4.7</td>
</tr>
<tr>
<td>Fat</td>
<td>1.5</td>
</tr>
<tr>
<td>Calcium</td>
<td>0.2</td>
</tr>
<tr>
<td>Moisture</td>
<td>5.5</td>
</tr>
<tr>
<td>pH</td>
<td>6.5-7.0</td>
</tr>
<tr>
<td>Solubility</td>
<td>99</td>
</tr>
</tbody>
</table>

### Codex specifications for caseinate*

<table>
<thead>
<tr>
<th>Component</th>
<th>Caseinate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
</tr>
<tr>
<td>Milkfat</td>
<td>-</td>
</tr>
<tr>
<td>Protein (db)</td>
<td>88.0%</td>
</tr>
<tr>
<td>Casein in protein</td>
<td>95.0%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
</tr>
<tr>
<td>Lactose**</td>
<td>-</td>
</tr>
<tr>
<td>Scorched particles</td>
<td>-</td>
</tr>
<tr>
<td>Spray</td>
<td>-</td>
</tr>
<tr>
<td>Roller</td>
<td>-</td>
</tr>
</tbody>
</table>

** Expressed in anhydrous form
**Manufacture of Caseinate**

Rennet casein → Lactic acid casein → Mineral acid casein

Water → 20 - 25% total solids slurry → pH 6.7, 60 - 75°C → Dissolved casein → Dry → Water → Sodium, Potassium and Calcium Caseinates

**Typical composition and characteristics**

**Potassium caseinate**
- Typical composition
  - Protein (db) 92%
  - Moisture 6%
  - Lactose <1%
  - Fat 2%
  - Ash 5%
  - Potassium 1.5%
  - Calcium 0.2%
- Characteristics: Color: white to cream, Flavor: bland, pH 6-7
- Storage: <25 C, <65% rh, 12-24 months

**Calcium Caseinate**
- Typical composition
  - Protein (db) 91%
  - Moisture 6%
  - Lactose <1%
  - Fat 1.5%
  - Ash 5%
  - Calcium 1.2%
- Characteristics: Color: white to cream, Flavor: bland, pH 6.6-7
- Storage: <25 C, <65% rh, 12-24 months

**Sodium caseinate**
- Typical composition
  - Protein (db) 92%
  - Moisture 6%
  - Lactose <1%
  - Fat 1.5%
  - Ash 5%
  - Sodium 1.2%
  - Calcium 0.2%
- Characteristics: Color: white to cream, Flavor: bland, pH 6.6-7
- Storage: <26 C, <65% rh, 12 months

**Ammonium caseinate**
- Typical composition
  - Protein (db) 91%
  - Moisture 6%
  - Lactose 1%
  - Fat 1.5%
  - Ash 5%
- Characteristics: Color: white to cream, Flavor: bland, pH 5.7-6.7
- Storage: <25 C, <65% rh
Co-precipitate

Co-precipitates consist of casein and whey protein complexes. Heat is used to cause the whey proteins and casein to interact. Acid or calcium salts then are used to precipitate the protein complexes.

Co-precipitates are classified according to their calcium content. The pH of the milk when the proteins coagulate determines the calcium content of the co-precipitate.

Co-precipitates are insoluble unless modified by alkali in a process similar to the conversion of casein into caseinates. Low and medium calcium co-precipitates can be converted into very soluble products. High calcium co-precipitates may not be converted into a completely soluble product. Functional properties of the soluble co-precipitate will depend on the calcium content.

Co-precipitates typically are not produced in the United States. Products similar to soluble co-precipitates produced outside of the United States include total milk protein (TMP™), soluble lacto-protein and milk proteinate.

Types
- Acid
- Medium calcium
- High calcium

Regulations
- None, product not defined

Co-precipitate composition

![Co-precipitate composition graph]

General composition of co-precipitate

<table>
<thead>
<tr>
<th>Component</th>
<th>Co-precipitate type</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Protein</td>
<td>86.7</td>
</tr>
<tr>
<td>Lactose</td>
<td>0.5</td>
</tr>
<tr>
<td>Ash</td>
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</tr>
<tr>
<td>Fat</td>
<td>0.9</td>
</tr>
<tr>
<td>Moisture</td>
<td>9.5</td>
</tr>
<tr>
<td>Calcium</td>
<td>0.54</td>
</tr>
<tr>
<td>pH</td>
<td>5.4-5.8</td>
</tr>
</tbody>
</table>
**Manufacture of Co-precipitate**

- **Pasteurized skim milk**
  - CaCl/acid
  - 85 - 95°C
    - 1 - 20 minutes
- **Separate**
  - Whey
- **Casein/whey protein aggregates**
  - Water
  - Wash/centrifuge
  - Water
- **Dry/grind**
  - Water
- **Co-Precipitate**

**Manufacture of Soluble Co-precipitate**

- **Co-precipitate**
  - Water
  - 20 - 25% total solids slurry
  - pH 6.7, 60 - 75°C
    - 30 - 60 minutes
- **Dilute alkali**
- **Casein/whey protein aggregates**
- **Dry**
  - Water
  - Soluble Co-Precipitate

**Typical composition and characteristics**

Not available
Milk Protein Concentrate (MPC) and Milk Protein Isolate (MPI)

Milk protein concentrates are not defined. For the purposes of this handbook, however, the following definitions will be used:

**UF milk** – liquid milk that has a portion of the lactose and mineral removed. The ratio of casein to whey protein is relatively unchanged from the original milk.

**Milk protein concentrate (MPC) and Milk protein isolate (MPI)** – the dry form of UF milk. MPCs typically range from 42 to 85% protein (dry basis). An MPC having 90% protein is referred to as a milk protein isolate (MPI).

MPCs/MPIs are produced by a pressure driven process using semipermeable membranes known as ultrafiltration (UF). Lactose and minerals are removed by UF until the desired protein content is reached. The portion that remains, that is, the concentrated protein fraction, is referred to as retentate, while the lactose and mineral stream is known as permeate.

Proteins are not denatured by the UF process, therefore, MPCs/MPIs are very soluble. Skim or whole milk may be used; however, MPCs/MPIs typically are produced with skim milk.

**Concentrated Milk Proteins (ADPI definition)** - are obtained by concentrating bovine skim milk through filtration processes so that the finished dry product contains 40% or more protein by weight. Concentrated Milk Protein products may be produced by filtration, dialysis or any other safe and suitable process by which all or part of the lactose and minerals may be removed. Products cannot be produced by combining separately produced casein (caseinate) and whey proteins.

Milk Protein Concentrate (MPC) (ADPI definition) - are produced by filtration methods (Ultrafiltration and Diafiltration) which capture essentially all the casein and whey proteins contained in the raw material stream in the finished product, resulting in a casein-to-whey protein ratio equivalent to that of the original milk, generally a value of 80:20. MPC has a protein content between 40 - 89.5%.

**MPC composition**

<table>
<thead>
<tr>
<th>Component</th>
<th>MPC 42</th>
<th>MPC 56</th>
<th>MPC 70</th>
<th>MPC 85</th>
<th>MPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>40.6</td>
<td>54.4</td>
<td>68.3</td>
<td>83.1</td>
<td>87.1</td>
</tr>
<tr>
<td>Lactose</td>
<td>45.5</td>
<td>31.7</td>
<td>18.2</td>
<td>3.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Ash</td>
<td>7.9</td>
<td>7.6</td>
<td>7.3</td>
<td>6.9</td>
<td>5.9</td>
</tr>
<tr>
<td>Fat</td>
<td>0.9</td>
<td>1.2</td>
<td>1.2</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Moisture</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>
ADPI industry standard for milk protein concentrate (MPC)/milk protein isolate (MPI)

<table>
<thead>
<tr>
<th>Component</th>
<th>Minimum/ maximum</th>
<th>MPC40</th>
<th>MPC42</th>
<th>MPC56</th>
<th>MPC70</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>minimum</td>
<td>39.5</td>
<td>41.5</td>
<td>55.5</td>
<td>69.5</td>
</tr>
<tr>
<td>Lactose</td>
<td>maximum</td>
<td>52.0</td>
<td>51.0</td>
<td>36.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Ash</td>
<td>maximum</td>
<td>10.0</td>
<td>10.0</td>
<td>10.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Fat</td>
<td>maximum</td>
<td>1.25</td>
<td>1.25</td>
<td>1.50</td>
<td>2.50</td>
</tr>
<tr>
<td>Moisture</td>
<td>maximum</td>
<td>5.0</td>
<td>5.0</td>
<td>5.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

ADPI industry standard for milk protein concentrate (MPC)/milk protein isolate (MPI)

<table>
<thead>
<tr>
<th>Component</th>
<th>Minimum/ maximum</th>
<th>MPC80</th>
<th>MPC85</th>
<th>MPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein*</td>
<td>minimum</td>
<td>79.5</td>
<td>85.0</td>
<td>89.5</td>
</tr>
<tr>
<td>Lactose</td>
<td>maximum</td>
<td>9.0</td>
<td>8.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Ash</td>
<td>maximum</td>
<td>8.0</td>
<td>8.0</td>
<td>8.0</td>
</tr>
<tr>
<td>Fat</td>
<td>maximum</td>
<td>2.50</td>
<td>2.50</td>
<td>2.50</td>
</tr>
<tr>
<td>Moisture</td>
<td>maximum</td>
<td>6.0</td>
<td>6.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

*Protein for MPC85 and MPI reported on a dry basis.
Typical composition and characteristics

**MPC 42**
- **Typical composition**
  - Protein (db): 42%
  - Moisture: 5%
  - Lactose: 46%
  - Fat: 1%
  - Ash: 8%
- **Characteristics**
  - Color: white to light cream
  - Flavor: clean, dairy
  - pH (5% solution): 6.5
- **Storage**
  - < 25 C, <65% rh
  - 12-18 months

**MPC 70**
- **Typical composition**
  - Protein (db): 70%
  - Moisture: 5%
  - Lactose: 17%
  - Fat: 1.4%
  - Ash: 7%
- **Characteristics**
  - Color: white to light cream
  - Flavor: clean, dairy
  - pH (5% solution): 6.5
- **Storage**
  - < 25 C, <65% rh
  - 12-18 months

**MPC 85**
- **Typical composition**
  - Protein (db): 85%
  - Moisture: 5%
  - Lactose: 3%
  - Fat: 1.5%
  - Ash: 7%
- **Characteristics**
  - Color: white to light cream
  - Flavor: clean, dairy
  - pH (5% solution): 6.5
- **Storage**
  - < 25 C, <65% rh
  - 12-18 months

**MPI**
- **Typical composition**
  - Protein (db): 90%
  - Moisture: 5%
  - Lactose: <1%
  - Fat: 1.5%
  - Ash: 6%
- **Characteristics**
  - Color: white to light cream
  - Flavor: clean, dairy
  - pH (5% solution): 6.5
- **Storage**
  - < 25 C, <65% rh
  - 12 months
Reduced Calcium Milk Protein Concentrate

Reduced calcium milk protein concentrates are a relatively new dairy ingredient and are not defined.

A general process for manufacture of a reduced calcium MPC uses ultrafiltration to remove lactose and minerals until the desired protein content is reached in a process similar to that used to produce regular MPCs. Because calcium typically is associated with the casein micelle, calcium does not permeate readily and therefore calcium concentrations in MPCs do not decrease as might otherwise be expected. Reducing the pH of milk causes calcium to be released from the casein micelle. One method for reducing the calcium content of a MPC would be to lower the pH of the milk through addition of acid followed by ultrafiltration to remove lactose, minerals (including calcium).

Proteins are not denatured by the UF process, therefore, reduced calcium MPCs are very soluble. The ratio of casein to whey proteins also is not altered. The product claims greater heat stability and a longer shelf life as compared to a regular MPC.

Regulations
♦ None, product not defined

Reduced calcium MPC composition

<table>
<thead>
<tr>
<th>Component</th>
<th>MPC 85</th>
<th>Red Ca MPC 85</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>83.1 %</td>
<td>82 %</td>
</tr>
<tr>
<td>Lactose</td>
<td>3.5 %</td>
<td>5 %</td>
</tr>
<tr>
<td>Ash</td>
<td>6.9 %</td>
<td>6.4 %</td>
</tr>
<tr>
<td>Fat</td>
<td>1.5 %</td>
<td>1.3 %</td>
</tr>
<tr>
<td>Moisture</td>
<td>5 %</td>
<td>5.3 %</td>
</tr>
<tr>
<td>Calcium</td>
<td>2,200 mg/100g</td>
<td>1,750 mg/100g</td>
</tr>
</tbody>
</table>

Manufacture of Reduced Calcium MPC
Manufacture of Reduced Calcium MPC

Typical composition and characteristics

**Reduced calcium MPC**

- **Typical composition**
  - Protein (db): 87%
  - Moisture: 5%
  - Lactose: 5%
  - Fat: 1%
  - Ash: 6%

- **Characteristics**
  - Color: white to light cream
  - Flavor: clean, sweet
  - pH: 6.7

- **Storage**
  - Ambient, <65% rh
  - 24 months

*Exact composition depends on manufacturer*
**Milk Permeate**

Milk permeate is not defined. For purposes of this handbook, however, the following definition will be used:

*Milk permeate* - portion of the milk that crosses or permeates an ultrafiltration (UF) membrane. Milk permeate contains lactose, minerals and nonprotein nitrogen (NPN). True protein typically is not present in significant amounts although some manufacturers include small molecular weight compounds that contain nitrogen as part of the protein content.

Milk permeate is a by product of MPC production.

Small molecular weight compounds such as galactose and lactic acid that are produced during cheese production are not present in milk permeate as compared to permeate produced from whey.

Manufacturers often do not distinguish permeate from milk as opposed to whey and unless listed otherwise it should be assumed that permeate is from whey rather than milk.

Product may be identified on the label as milk permeate or dairy product solids. Other names could include modified whey, deproteinized whey, dried whey product or dried whey product solubles.

*Dairy permeate* (ADPI definition) - produced by the removal of protein and other solids from milk or whey resulting in a product with a high concentration of lactose. Removal of the dairy constituents is accomplished by physical separation techniques such as filtration and diafiltration. The acidity of Dairy Permeate may be adjusted by the addition of safe and suitable pH adjusting ingredients. Dairy Permeate meets the definition of Dairy Product Solids, which is the subject of a GRAS notification to the U.S. Food and Drug Administration and complies with all provisions of the U.S. Federal Food, Drug and Cosmetic Act.

**Milk permeate composition**

<table>
<thead>
<tr>
<th></th>
<th>Percentage of total solids (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NFDM</strong></td>
<td></td>
</tr>
<tr>
<td>Fat</td>
<td>0</td>
</tr>
<tr>
<td>Ash</td>
<td>20</td>
</tr>
<tr>
<td>Lactose</td>
<td>40</td>
</tr>
<tr>
<td>Protein</td>
<td>80</td>
</tr>
<tr>
<td><strong>Milk permeate</strong></td>
<td></td>
</tr>
<tr>
<td>Fat</td>
<td>0</td>
</tr>
<tr>
<td>Ash</td>
<td>20</td>
</tr>
<tr>
<td>Lactose</td>
<td>40</td>
</tr>
<tr>
<td>Protein</td>
<td>80</td>
</tr>
</tbody>
</table>

**Regulations**

- None, product not defined
- GRAS status

ADPI Industry Standard
General composition of milk permeate

<table>
<thead>
<tr>
<th>Component</th>
<th>Milk permeate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>&lt;3</td>
</tr>
<tr>
<td>Lactose</td>
<td>85</td>
</tr>
<tr>
<td>Ash</td>
<td>9</td>
</tr>
<tr>
<td>Fat</td>
<td>0</td>
</tr>
<tr>
<td>Moisture</td>
<td>3</td>
</tr>
</tbody>
</table>

ADPI industry standard for milk permeate

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>3 - 5</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Lactose</td>
<td>78 - 88</td>
<td>76</td>
<td>-</td>
</tr>
<tr>
<td>Ash</td>
<td>8 - 11</td>
<td>-</td>
<td>14</td>
</tr>
<tr>
<td>Fat</td>
<td>0 - 1.0</td>
<td>-</td>
<td>1.5</td>
</tr>
<tr>
<td>Moisture</td>
<td>3 - 4.5</td>
<td>-</td>
<td>5.0</td>
</tr>
</tbody>
</table>
Manufacture of Milk Permeate

**Typical composition and characteristics**

**Milk Permeate**

- **Typical composition**
  - Protein (db): 3%
  - Moisture: 2%
  - Lactose: 85%
  - Fat: 0%
  - Ash: 9%

- **Characteristics**
  - Color: white to yellow cream
  - Flavor: slightly milky, slightly sweet
  - pH: 6.3

- **Storage**
  - < 25 C, < 65% rh
  - 12 months

* Non protein nitrogen included in this value. May or may not contain true protein.
**Micellar Casein**

Micellar casein is not defined. For the purposes of this handbook, however, the following definitions will be used:

**Microfiltered (MF) milk** – liquid milk that has a portion of the whey protein, lactose and mineral removed. The ratio of casein to whey proteins is altered such that a greater portion of casein is present in MF milk than in typical milk.

**Micellar casein** – the dry form of MF milk.

Another term for micellar casein may be native phosphocasein.

Micellar casein is produced by a pressure driven process using semipermeable membranes known as microfiltration (MF). Whey proteins, lactose and minerals are removed until the desired casein content is reached. The portion that remains, that is, the concentrated casein fraction, is referred to as retentate, while the whey protein, lactose and mineral stream is known as permeate. Because whey proteins are removed the ratio of casein to whey proteins is altered from that found in milk.

Casein is present in milk in the form of micelles. The MF process does not alter the structure of the micelles; therefore, MF milk with micellar casein is very soluble.

Micellar casein typically is produced from skim milk.

The permeate produced by the MF process has a very different composition from UF permeate.

Native whey proteins are a byproduct of this process.

**Micellar Casein (ADPI definition)** - is produced using Microfiltration, which will alter the casein-to-whey protein ratio compared to that found in milk. The casein-to-whey protein ratio typically ranges between 82:18 and 95:5 for commercially available products.

---

**Regulations**

- None, product not defined
**Manufacture of Micellar Casein**

Typical composition and characteristics

**Micellar Casein # 1**
- Typical composition
  - Protein (db) 86%
  - Moisture 5%
  - Lactose 4%
  - Fat 1%
  - Ash 8%
  - Casein to total protein 92%
- Characteristics
  - Color: white to light cream
  - Flavor: clean, dairy
  - Solubility: 99%
  - pH (10% solution) 6.5
- Storage
  - < 25 C, <65% rh
  - 24 months

**Micellar Casein # 2**
- Typical composition
  - Protein (db) 89%
  - Moisture 5%
  - Lactose <0.5%
  - Fat 2%
  - Ash 8%
  - Casein to total protein na
- Characteristics
  - Color: white to light cream
  - Flavor: clean, dairy
  - Solubility: 99%
  - pH (10% solution) 7.1
- Storage
  - < 25 C, <65% rh

*Exact composition depends on manufacturer*
Native Whey Protein

Native whey proteins are not defined. For the purposes of this handbook, however, the following definition will be used:

**Native whey protein** – whey proteins that have been removed from milk by the process of MF/UF. Native whey proteins have not been through the cheese making process.

Other terms for native whey proteins may include serum proteins and ideal whey although none of these terms have a standard definition.

Native whey proteins are a by product of micellar casein production.

Native whey proteins may be concentrated by UF, through removal of lactose and minerals, to any desired protein level.

**Regulations**
- None, product not defined

### Presence of components in cheese whey versus MF permeate whey

<table>
<thead>
<tr>
<th>Component</th>
<th>Cheese whey</th>
<th>MF permeate whey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starter cultures</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Rennet</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Glycomacropeptide</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Pasteurization steps</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Fat/phospholipids</td>
<td>Yes</td>
<td>Negligible</td>
</tr>
<tr>
<td>pH</td>
<td>&lt;6.5</td>
<td>6.6</td>
</tr>
</tbody>
</table>
Manufacture of Native Whey Protein

Typical composition and characteristics

Native whey protein

- Typical composition
  - Protein (db) 92%
  - Moisture 5%
  - Lactose 2%
  - Fat 0.5%
  - Ash 3%

- Characteristics
  - Color: white to light cream
  - Flavor: clean, dairy
  - Solubility: 99%
  - pH (10% solution) 6.0

- Storage
  - Not available
Manufacturing Dairy Ingredients from Whey

Whey

Concentrate

Fractionate

Protein

Ultrafiltration

Whey

Whey permeate

Whey proteins

Lactalbumin

Individual proteins

Whey protein isolate

Lactose

Crystallization

Precipitation

Ion exchange

Chromatography

Dairy Minerals

Minerals

Hydrolyze

Ion exchange/Electrodialysis

Chemically alter

Whey proteins

Heat stable whey protein concentrate

Whey protein isolate

Whey protein phospholipid concentrate

Alpha-lactalbumin enriched

Galacto-oligosaccharides

Whey protein isolate

Reduced lactose whey

Lactose hydrolyzed

Lactose hydrolyzed

Lactose derivatives

Whey protein isolate

Heat stable whey protein concentrate

Demineralized whey

Heat stable whey protein concentrate

Microfiltration

Modify

Lactose

 Modify

Demineralized whey

Demineralized whey

Whey protein isolate

Whey protein phospholipid concentrate

Whey protein isolate

Galacto-oligosaccharides

Lactose hydrolyzed

Chemically altered
Whey

Cheesemaking and whey production

Whey is a by product of cheese manufacture. Approximately 9 pounds of whey are produced for every 1 pound of cheese. Although there are many types of cheese the resulting wheys often are quite similar.

Cheese may be produced through use of enzymes, such as rennet, that clot casein or addition of acid to lower the pH of the milk so that casein will precipitate. Some types of cheese use both methods to clot the casein.

Cheese and the resulting whey can be grouped into one of two general categories depending on whether the curd was formed by rennet which clots the casein or acid which precipitates the casein.

Sweet whey cheeses – most cheese types including Cheddar, Mozzarella, Swiss and Brick.

Acid whey cheeses – Cottage, ricotta, quark and cream cheese and industrial casein made by acid coagulation

When looking at the products from the standpoint of whey, whey drawn from curd that is clotted by rennet only will have a higher pH and is considered to be sweet whey. Whey drawn from curd that has formed through the use of acid (with or without added rennet) will have a lower pH and is referred to as acid whey.

An additional type of whey would be fermented whey. Fermented whey is sweet whey that has a lower pH due to the action of cheese starter culture. Fermented whey is not typically produced but rather results from undesired continued acid production by starter cultures.
The distribution of milk components between cheese and whey is given below. Casein and fat are found largely in the cheese, while lactose, whey proteins and water partition mainly into the whey. It should be noted that the total solids of the milk are divided almost evenly between the cheese and resulting whey.

The following figure is a comparison of solids composition of milk and whey. Milk contains greater amounts of fat and protein while milk and whey are similar in lactose and mineral content.

Distribution of milk components during cheese manufacture

Composition of milk and whey

<table>
<thead>
<tr>
<th>Component</th>
<th>Milk</th>
<th>Whey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td>4</td>
<td>0.5</td>
</tr>
<tr>
<td>Protein</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Lactose</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Minerals</td>
<td>1</td>
<td>0.5</td>
</tr>
</tbody>
</table>
A comparison of milk, sweet whey and acid whey on an as is basis is given in the next table. Milk typically has twice the total solids, 4.5 times the protein and 10 times the fat as sweet or acid wheys. Lactose and mineral contents at all three are relatively similar. The lactic acid content of acid whey is greater than either milk or sweet whey because of the production of acid by cheese cultures during formation of the cheese curd.

**Comparison of milk and sweet and acid whey**

<table>
<thead>
<tr>
<th>Component</th>
<th>Milk</th>
<th>Sweet whey</th>
<th>Acid whey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total solids</td>
<td>12.5</td>
<td>6.5</td>
<td>6.5</td>
</tr>
<tr>
<td>Protein</td>
<td>3.5</td>
<td>0.8</td>
<td>0.7</td>
</tr>
<tr>
<td>Lactose</td>
<td>4.8</td>
<td>4.8</td>
<td>4.4</td>
</tr>
<tr>
<td>Ash</td>
<td>0.7</td>
<td>0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>Fat</td>
<td>3.5</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>—</td>
<td>0.1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Sweet</th>
<th>Acid</th>
<th>Greek yogurt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total solids</td>
<td>6.3</td>
<td>6.4</td>
<td>5.7</td>
</tr>
<tr>
<td>Protein</td>
<td>0.8</td>
<td>0.5</td>
<td>0.3*</td>
</tr>
<tr>
<td>Lactose</td>
<td>4.9</td>
<td>4.4</td>
<td>4.2</td>
</tr>
<tr>
<td>Minerals</td>
<td>0.5</td>
<td>0.6</td>
<td>0.7</td>
</tr>
</tbody>
</table>

**Comparison of sweet, acid and Greek yogurt acid wheys**

<table>
<thead>
<tr>
<th>Component</th>
<th>Sweet</th>
<th>Acid</th>
<th>Greek yogurt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>45</td>
<td>103</td>
<td>123</td>
</tr>
<tr>
<td>pH</td>
<td>~6.0</td>
<td>&lt; 5.5</td>
<td>~ 4.2</td>
</tr>
</tbody>
</table>

*Based on nitrogen content so nonprotein nitrogen included.

Sweet or acid whey that was produced from cheese where the pH was reduced by microbial cultures will contain byproducts of the fermentations such as galactose and lactic acid. Whey produced from cheese that used direct addition of acid will contain the acid used rather than fermentation byproducts. Acids typically used include: glucono-δ-lactone, lactic, sulfuric, phosphoric, hydrochloric and citric.

Fermented whey will not have higher calcium levels but will contain byproducts of starter culture fermentations.

Greek yogurt acid whey is a byproduct of Greek yogurt manufacture and is a special type of acid whey. Because of the high heat used to incorporate the whey proteins into the structure of the yogurt, Greek yogurt acid whey typically contains little to no true protein. The pH of the Greek yogurt when the whey is removed is lower than the pH of an acid cheese at whey removal so Greek yogurt acid whey will have a higher calcium content than either sweet or acid whey.

**Compositional differences**

The composition of the sweet and acid whey differs because of the pH of the whey and the use of rennet.

Sweet whey will contain glycomacropeptide (GMP). Rennet cleaves κ-casein thereby producing a protein fragment known as GMP. Glycomacropeptide can be 20% of the protein in sweet whey and it is not present in acid whey unless rennet is used. GMP is also know as casein macropeptide (CMP).

Acid whey will have higher levels of calcium than sweet whey. Calcium phosphate is more soluble at lower pHs therefore the lower pH of acid whey will draw more calcium from the cheese curd into the whey than sweet whey.
**Whey processing**

The cheese maker typically removes cheese fines and whey cream from the whey before it is processed.

Cheese fines are small pieces of cheese that were not captured in the curd. Cheese fines consist of coagulated casein and are not soluble, therefore their presence in whey is not desired.

Whey cream consists of small fat globules that were not trapped within the cheese matrix. These fat globules can cause off flavors during storage of whey based powders; therefore, it is important that as much of the whey cream be removed as possible.

The majority of whey is produced from pasteurized milk. Regardless of whether the whey came from raw or pasteurized milk, all whey must be pasteurized before it may be further processed into a dairy ingredient.

**Optional steps**

- **Bleaching** – benzoyl or hydrogen peroxide may be added to reduce the yellow/orange color of whey resulting from the use of annatto color during cheese manufacture.
- **Neutralizing** – addition of caustic to increase the pH of the whey. Neutralizing typically would be used only for acid or fermented whey.
- **Crystallization** – concentrated whey is allowed to cool so that lactose crystallizes. Lactose can exist in several forms - α-monohydrate, β and glass or amorphous. The glass or amorphous form of lactose is very hygroscopic (water loving) and tends to pick up water during storage that can lead to clumping of the powder. Lactose crystallized in the α-monohydrate form is less hygroscopic than lactose in glass form. The majority of whey powder produced in the US has a crystallization step so that the resulting powder is non hygroscopic.

**Type of dryer used**

Whey powder functionality is affected by the type of dryer used. Majority of whey powder is produced by spray drying which is a less severe process than roller drying.

Roller drying is relatively uncommon because of the amount of protein denaturation that results. Roller dried product will have a flaked appearance, browner color and more cooked flavor as compared to sprayed dried powder.

**Final form of powder**

Agglomeration is used to increase particle size and is a step in the instantizing process.

Instantizing improves the ability of powder to disperse and dissolve quickly. A surfactant such as lecithin may be added to improve the ability of water to contact powder particles in the presence of lipids (fat).

Agglomeration and instantizing do not improve powder solubility. Rather they increase the rate of powder dispersing and dissolving. Powder that is insoluble will not be made soluble if agglomerated or instantized.

Agglomerated/instantized powder typically will have a shorter shelf life as compared to ordinary powder because of the additional heat used during processing.
Assumptions used in this booklet when describing whey for further processing

- Cheese fines removed
- Whey cream removed
- Whey has been pasteurized

Types
- Sweet whey
- Acid whey

Grade
- Extra
- Grade not assignable

Dryer used
- Roller
- Spray

Final form
- Ordinary, hygroscopic
- Ordinary, non hygroscopic
  (non-agglomerated, non-instant)
- Agglomerated
- Instantized

Regulations
- Liquid whey
  21 CFR 184.1979
- Concentrated whey
  21 CFR 184.1979
- Dry whey
  21 CFR 184.1979

United States Standards for Dry Whey
USDA, AMS - Dairy Division, December 14, 2000


ADPI Industry Standard

**Whey Definitions**
(summarized from Code of Federal Regulations)

**Whey** is the liquid obtained by separating the coagulum from milk, cream, or skim milk in cheese making. Acidity may be adjusted with safe and suitable pH adjusting ingredients.

**Sweet whey** is whey that has an insignificant conversion of lactose to lactic acid. Maximum titratable acidity of not greater than 0.16% and alkalinity of ash not greater than 225 ml of 0.1 HCl.

**Concentrated whey** is whey where a portion of the water has been removed leaving all other constituents in the same relative proportions.

**Dry whey** is fresh whey that has been pasteurized and contains all constituents, except water, in the same proportions as found in the original whey. Preservatives are not permitted.

**Dry sweet whey** shall not have greater than 0.16 percent titratable acidity on a reconstituted basis.

**Dry acid whey** shall have greater than 0.35 percent titratable acidity on a reconstituted basis.

**Animal Feed Definitions** (Association of Animal Feed Control Officials)

**Whey** is the product obtained as a fluid by separating the coagulum from milk, cream, or skim milk and from which a portion of the milkfat may have been removed.

**Dried Whey** is the product obtained by removing water from whey. It contains not less than 11% protein nor less than 61% lactose.

**Dried Cultured Whey Product** is the product obtained by drying whey from which a portion of the lactose, protein and/or minerals has been removed and which has been cultured.
Possible Certifications for Whey

There are additional categories or certifications possible for whey including organic, Grade A, cow/sheep/goat/mixed, kosher and halal. Sweet, acid and fermented whey may fall into any, several or none of these categories.

Organic
Organic whey must meet regulations for organic products as defined by the United States Department of Agriculture (USDA) in the Code of Federal Regulations (CFR). Auditors ensure compliance. Practices are designed to ensure segregation of organic and nonorganic product within a processing plant and use of organic ingredients, such as defoamer, in organic whey products.

Grade "A"
Grade "A" whey products must be produced from Grade "A" milk. The plant that produces the products also must be Grade "A". The designation of Grade "A" focuses on aspects such as design of equipment, product sampling, water quality and handling, dairy farm construction, cleaning/sanitizing procedures, product testing, employee training, etc., with plant inspections to ensure compliance.

Grade "A" is outlined in the "Grade A" Pasteurized Milk Ordinance. The document is produced by the United States Public Health Services (USPHS) and Food and Drug Association (FDA).

Mixed
Cow, sheep and goat refer to the type of milk used to manufacture the cheese and resulting whey. Mixed means the cheese/whey was made from milk from more than one species. For example, cow and sheep milk may have been blended together to produce the cheese and whey.

Kosher
Kosher refers to foods that conform to the rules of kashrut (Jewish dietary law). Kosher whey must meet the rules of the rabbinical organization giving approval. Several organizations oversee the application of kosher requirements. Circle K and Circle U are two examples. The letter "D" along with the symbol for the rabbinical organization indicates the product is dairy.

Kosher whey often comes from cheese that is not designated as kosher. All of the components of the cheese are kosher, however, the cheese itself has not been certified as kosher. The whey from such cheese is still considered kosher. The majority of the whey in the U.S. is kosher.

Halal
Halal refers to things that are permitted under Islamic law. Milk is considered halal although the addition of certain ingredients can make it forbidden or haram. An example of a forbidden ingredient would be flavorings that contain alcohol.

Whey and whey products produced in the U.S. typically are certified halal. An example of a group involved in halal certification of dairy products is the Islamic Food and Nutrition Council of America (IFNCA). Symbols on dairy packages representing halal certification often contain the crescent moon image.
General composition of whey powders

<table>
<thead>
<tr>
<th>Component</th>
<th>Sweet whey</th>
<th>Acid whey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>12.5</td>
<td>12.0</td>
</tr>
<tr>
<td>Lactose</td>
<td>73</td>
<td>70</td>
</tr>
<tr>
<td>Ash</td>
<td>8.5</td>
<td>12</td>
</tr>
<tr>
<td>Fat</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Moisture</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

USDA specifications for US Grades of dry whey*

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
</tr>
<tr>
<td>Milkfat -</td>
<td>-</td>
</tr>
<tr>
<td>Moisture -</td>
<td>-</td>
</tr>
<tr>
<td>Titratable acidity</td>
<td>-</td>
</tr>
<tr>
<td>sweet (dry)</td>
<td>-</td>
</tr>
<tr>
<td>acid (dry)</td>
<td>0.35%</td>
</tr>
<tr>
<td>Scorch</td>
<td>-</td>
</tr>
<tr>
<td>Bacteria (spc/g)</td>
<td>-</td>
</tr>
<tr>
<td>Coliform (10/g)</td>
<td>-</td>
</tr>
</tbody>
</table>

Optional test requirements

<table>
<thead>
<tr>
<th>Component</th>
<th>Extra grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>11%</td>
</tr>
<tr>
<td>Alkalinity of ash (sweet)</td>
<td>-</td>
</tr>
</tbody>
</table>

* United States Standards for Dry Whey
USDA, AMS - Dairy Division, December 14, 2000

Additional Requirements

Physical Appearance - Uniform color, free flowing, free from lumps that do no break up under slight pressure and practically free from visible dark particles.

Flavor - Normal whey flavor and free from undesirable flavors. May have the following flavors to a slight degree: bitter, fermented, storage and utensil. May have the following flavors to a definite degree: feed and weedy.
Grade A whey products must comply with the requirements in the United States Public Health/Food and Drug Association (USPH/FDA) Grade A Pasteurized Milk Ordinance (PMO). Grade A whey products must come from cheese made with Grade A raw milk and processed to meet the standards given in the PMO.

### Requirements for Grade A dry whey

<table>
<thead>
<tr>
<th>Standard</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Cooled to 45°F or less during crystallization within 18 h of condensing</td>
</tr>
<tr>
<td>Phosphatase</td>
<td>Less than 1 microgram/ml</td>
</tr>
<tr>
<td>Bacterial limit</td>
<td>30,000/g</td>
</tr>
<tr>
<td>Coliform limit</td>
<td>10/g</td>
</tr>
<tr>
<td>Drugs</td>
<td>No zone equal to or greater than 16 mm</td>
</tr>
</tbody>
</table>

### Codex specifications for sweet whey powder*

<table>
<thead>
<tr>
<th>Component</th>
<th>Minimum</th>
<th>Reference content</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>-</td>
<td>61.0</td>
<td>-</td>
</tr>
<tr>
<td>Milk protein</td>
<td>10.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Milk fat</td>
<td>-</td>
<td>2.0</td>
<td>-</td>
</tr>
<tr>
<td>Water</td>
<td>-</td>
<td>-</td>
<td>5.0</td>
</tr>
<tr>
<td>Ash</td>
<td>-</td>
<td>-</td>
<td>9.5</td>
</tr>
<tr>
<td>pH (in 10% solution)</td>
<td>&gt; 5.1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>pH (or titratable acidity)</td>
<td>-</td>
<td>-</td>
<td>0.35%</td>
</tr>
</tbody>
</table>


### Codex specifications for acid whey powder*

<table>
<thead>
<tr>
<th>Component</th>
<th>Minimum</th>
<th>Reference content</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>-</td>
<td>61.0</td>
<td>-</td>
</tr>
<tr>
<td>Milk protein</td>
<td>7.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Milk fat</td>
<td>-</td>
<td>2.0</td>
<td>-</td>
</tr>
<tr>
<td>Water</td>
<td>-</td>
<td>-</td>
<td>4.5</td>
</tr>
<tr>
<td>Ash</td>
<td>-</td>
<td>-</td>
<td>15.0</td>
</tr>
<tr>
<td>pH (in 10% solution)</td>
<td>-</td>
<td>-</td>
<td>5.1</td>
</tr>
<tr>
<td>pH (or titratable acidity)</td>
<td>0.35%</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### CFR specifications for dry whey*

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>0.2%</td>
<td>2%</td>
</tr>
<tr>
<td>Protein</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Lactose</td>
<td>61%</td>
<td>75%</td>
</tr>
<tr>
<td>Ash</td>
<td>7%</td>
<td>14%</td>
</tr>
<tr>
<td>Moisture</td>
<td>1%</td>
<td>8%</td>
</tr>
</tbody>
</table>

* 21 CFR 184.1979

### General Process for Manufacture of Whey

1. **Whey** (clarified and pasteurized)
2. Evaporate
3. Cool
4. **Liquid whey** (protein, minerals, fat and crystallized lactose)
5. Spray Dry
6. Non Hygroscopic Whey

### ADPI industry standard for extra grade for dry sweet whey

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>-</td>
<td>1.5%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>5%</td>
</tr>
<tr>
<td>Titratable acidity*</td>
<td>-</td>
<td>0.16%</td>
</tr>
</tbody>
</table>

*Used for classification purposes only. Not for grade determination.

### ADPI industry standard for extra grade for dry acid whey

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>-</td>
<td>1.5%</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>5%</td>
</tr>
<tr>
<td>Titratable acidity*</td>
<td>0.35%</td>
<td>-</td>
</tr>
</tbody>
</table>

*Used for classification purposes only. Not for grade determination.
Manufacture of Sweet and Acid Whey

Sweet whey
- Typical composition
  - Protein (db): 13%
  - Moisture: 5%
  - Lactose: 73%
  - Fat: 1%
  - Ash: 8%
- Characteristics
  - Color: off white to cream
  - Flavor: whey, slight salty
  - pH: 5.7 - 6.0
- Storage
  - < 27°C, <65% rh
  - 6 - 12 months

Acid whey
- Typical composition
  - Protein (db): 13%
  - Moisture: 5%
  - Lactose: 70%
  - Fat: 1%
  - Ash: 12%
- Characteristics
  - Color: off white to cream
  - Flavor: whey, slight salty
  - pH: 4.5
  - TA: 0.35 - 0.44%
- Storage
  - < 27°C, <65% rh
  - 6 - 12 months

Product Labeling
Dry Sweet Whey or Dry Acid Whey or Dry Whey _____ % titratable acidity (for dry whey over 0.16% but below 0.35% titratable acidity on a reconstituted basis)
Demineralized or Reduced Minerals Whey (RMW)

Processes such as precipitation, ion exchange, electrodialysis and membrane filtration may be used to remove minerals from whey. Membrane filtration, ion exchange and electrodialysis do not denature proteins thereby preserving protein solubility in demineralized whey produced by such methods. The exact process used will determine the mineral profile of the final product. Demineralized whey often will have a less salty flavor because of the reduced mineral concentration.

Demineralized or reduced minerals whey (ADPI definition) - Whey with a portion of the minerals removed by physical separation techniques such as precipitation, filtration or dialysis. The dry product cannot contain more than 7% ash. Acidity may be adjusted with safe and suitable pH adjusting ingredients.

CFR requires product to be listed as reduced minerals whey.

Types
- 25, 50 and 90% demineralization is typical

Regulations
- 21 CFR 184.1979

ADPI Industry Standard

Animal Feed Definition (Association of Animal Feed Control Officials)
Dried (dry) whey product - is the product obtained by dryng whey from which a portion of the lactose, protein and/or minerals have been removed. The minimum percent of crude protein and lactose and maximum percent ash must be prominently declared on the label. May also be labeled as "dried reduced minerals whey" or "dried reduced lactose whey," if appropriate.

Composition of demineralized whey *

<table>
<thead>
<tr>
<th>Component</th>
<th>Whey</th>
<th>25% Demin</th>
<th>50% Demin</th>
<th>90% Demin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Fat</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Protein</td>
<td>30</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Lactose</td>
<td>186</td>
<td>186</td>
<td>186</td>
<td>186</td>
</tr>
<tr>
<td>Ash</td>
<td>21</td>
<td>17</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>250</td>
<td>245</td>
<td>239</td>
<td>230</td>
</tr>
<tr>
<td>Ash in whey</td>
<td>8.6</td>
<td>7.0</td>
<td>4.6</td>
<td>0.9</td>
</tr>
</tbody>
</table>

* Values are in grams to illustrate the effect of mineral reduction on composition

Demineralized whey composition

Percentage of total solids (%)
**General composition of demineralized whey**

<table>
<thead>
<tr>
<th>Component</th>
<th>25% Demin</th>
<th>50% Demin</th>
<th>90% Demin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>12</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Lactose</td>
<td>77</td>
<td>78</td>
<td>80</td>
</tr>
<tr>
<td>Ash</td>
<td>5</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Fat</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Moisture</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

**CFR specifications for reduced minerals whey**

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Protein</td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td>Lactose</td>
<td>-</td>
<td>85</td>
</tr>
<tr>
<td>Ash</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>Moisture</td>
<td>1</td>
<td>6</td>
</tr>
</tbody>
</table>

* 21 CFR 184.1979

**ADPI industry standard for demineralized whey**

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>11.0 - 15.0</td>
<td>-</td>
<td>17</td>
</tr>
<tr>
<td>Lactose</td>
<td>70.0 - 80.0</td>
<td>-</td>
<td>82</td>
</tr>
<tr>
<td>Ash</td>
<td>1.0 - 7.0</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>Fat</td>
<td>0.5 - 1.8</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Moisture</td>
<td>3.0 - 4.0</td>
<td>-</td>
<td>5</td>
</tr>
</tbody>
</table>

**General Process for Manufacture of Demineralized Whey**

1. **Whey**
2. **Electrodialysis**
3. **Brine (minerals)**
4. **Evaporate**
5. **Water**
6. **Crystallize**
7. **Spray Dry**
8. **Water**
9. **Deimninalized Whey**

**Process Steps**

- Electrodialysis
- Evaporate
- Crystallize
- Spray Dry
Manufacture of Demineralized Whey

Dried Dairy Ingredients

Typical composition and characteristics

25% demineralized whey
- Typical composition
  - Protein (db) 11.4%
  - Moisture 5%
  - Lactose 78%
  - Fat 1%
  - Ash 5%
- Characteristics
  - Color: cream to dark cream
  - Flavor: less salty whey flavor
- Storage
  - < 27°C, <75% rh
  - 24 months

50% demineralized whey
- Typical composition
  - Protein (db) 11.5%
  - Moisture 5%
  - Lactose 80%
  - Fat 1%
  - Ash 3%
- Characteristics
  - Color: cream to dark cream
  - Flavor: not salty whey flavor
  - pH 6.0 – 6.5
- Storage
  - < 27°C, <75% rh
  - 24 months

90% demineralized whey
- Typical composition
  - Protein (db) 13.7%
  - Moisture 5%
  - Lactose 80%
  - Fat 1%
  - Ash 1%
- Characteristics
  - Color: cream to dark cream
  - Flavor: not salty whey flavor
  - pH 6.7
- Storage
  - < 27°C, <75% rh
  - 24 months

Product Labeling
Reduced Minerals Whey (_____ % minerals)

The percent of minerals is declared in 2% increments OR as actual percentage provided an analysis of the product is supplied.
Reduced Lactose Whey

Reduced lactose whey is produced by removing a portion of the lactose in the whey. Crystalline lactose is a byproduct. The mineral components of the whey are not altered.

Reduced lactose whey differs from whey protein concentrate (WPC) in that the minerals are not removed while production of WPCs involves removal of both lactose and minerals.

Because only lactose is removed, lactose reduced whey may also be referred to as mineral concentrated whey or fractionated whey.

Reduced lactose whey (ADPI definition) - Lactose content of the final dry product cannot exceed 60%. Removal of lactose may be accomplished by physical separation techniques such as precipitation, filtration or dialysis. Acidity may be adjusted with safe and suitable pH adjusting ingredients.

Regulations
• 21 CFR 184.1979

ADPI Industry Standard

Animal Feed Definition (Association of Animal Feed Control Officials)
Dry hydrolyzed whey - is the product obtained by drying whey from which a portion of the lactose, protein and/or minerals have been removed. The minimum percent of crude protein and lactose and maximum percent ash must be prominently declared on the label. May also be labeled as "dried reduced minerals whey" or "dried reduced lactose whey," if appropriate.
**CFR specifications for reduced lactose whey**

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Protein</td>
<td>16</td>
<td>24</td>
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<tr>
<td>Lactose</td>
<td>-</td>
<td>60</td>
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<tr>
<td>Ash</td>
<td>11</td>
<td>27</td>
</tr>
<tr>
<td>Moisture</td>
<td>1</td>
<td>6</td>
</tr>
</tbody>
</table>

* 21 CFR 184.1979

**ADPI industry standard for reduced lactose whey**

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>---------</td>
<td>-------</td>
<td>--------</td>
</tr>
<tr>
<td>Protein</td>
<td>18.0 - 24.0</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>Lactose</td>
<td>52.0 - 58.0</td>
<td>-</td>
<td>60</td>
</tr>
<tr>
<td>Ash</td>
<td>11.0 - 22.0</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Fat</td>
<td>1.0 - 4.0</td>
<td>-</td>
<td>24</td>
</tr>
<tr>
<td>Moisture</td>
<td>3.0 - 4.0</td>
<td>-</td>
<td>5</td>
</tr>
</tbody>
</table>

**General Process for Manufacture of Reduced Lactose Whey**

1. **Whey**
2. **Evaporate** → **Water**
3. **Crystallize**
4. **Decant (Separate)** → **Crystals (lactose)**
5. **Liquid whey (protein, minerals and some lactose)**
6. **Spray Dry** → **Reduced Lactose Whey**
Manufacture of Reduced Lactose Whey

Typical composition and characteristics

Reduced lactose whey*

- Typical composition
  - Protein (db) 24%
  - Moisture 4%
  - Lactose 56%
  - Fat 2%
  - Ash 15%

- Characteristics
  - Color: cream to dark cream
  - Flavor: typical whey
  - Storage < 27 C, <65% rh
  - 12 months

Mineral concentrated whey*

- Typical composition
  - Protein (db) 21.3%
  - Moisture 3%
  - Lactose 56%
  - Fat 2%
  - Ash 17%

- Characteristics
  - Color: cream to dark cream
  - Flavor: typical whey
  - Storage < 27 C, <65% rh
  - 12 months

*Exact composition depends on specifications

Product Labeling
Reduced Lactose Whey ( _____ % lactose)

The percent of lactose is declared in 5% increments OR as actual percentage provided an analysis of the product is supplied.
Lactose Hydrolyzed Whey

Lactose hydrolyzed whey is produced by hydrolyzing a portion of the lactose to glucose and galactose by addition of lactase enzyme. The product will have increased sweetness and decreased tendency for lactose crystallization as compared to whey. The amount of lactose converted to glucose and galactose depends on product specifications.

Lactose hydrolyzed whey is difficult to dry and the powder may tend to become sticky with storage.

Regulations
♦ None, product not defined

Animal Feed Definition (Association of Animal Feed Control Officials)
Dried Hydrolyzed Whey - is the residue obtained by drying lactase enzyme hydrolyzed whey. It contains a minimum of 30% total of glucose and galactose.

![General Process for Manufacture of Lactose Hydrolyzed Whey](image)
Manufacture of Lactose Hydrolyzed Whey

- Pasteurized Fluid Whey
- Lactase Addition
- Lactase Inactivation
- Evaporate
- Spray Dry
- Lactose Hydrolyzed Whey Powder

Typical composition and characteristics
Not available
**Protein Hydrolyzed Whey**

Protein hydrolyzed whey has a portion of the whey protein hydrolyzed into smaller fragments. Enzymes such as trypsin, chymotrypsin, etc. are used.

There is considerable variation in the product profile which typically is application driven. Protein hydrolyzed whey products designed for heat stability often will have less hydrolysis (larger molecular weight fragments) than products for infant nutrition.

The specific enzymes used, sequence of enzymes, reaction time, reaction temperature, etc are all important and can affect the type of protein fragments produced.

Manufacturers typically use whey protein concentrates (WPC) as starting material to produce protein hydrolyzed products with higher protein contents. The whey protein concentrates may be derived from either whey or milk (native whey protein).

**Regulations**
- None, product not defined
Manufacture of Protein Hydrolyzed Whey

Typical composition and characteristics

Hydrolyzed WPC 80 #1*
- Typical composition
  - Protein (db) 81%
  - Moisture 4%
  - Lactose 4%
  - Fat 6%
  - Ash 4%
- Characteristics
  - Color: cream
  - Flavor: na
- Storage
  - < 25 C, <75% rh
  - 24 months

Hydrolyzed WPC 80 #2*
- Typical composition
  - Protein (db) 81%
  - Moisture 4%
  - Lactose na%
  - Fat 5%
  - Ash 3%
- Characteristics
  - Color: cream
  - Flavor: na
- Storage
  - < 27 C, <75% rh

Hydrolyzed WPI*
- Typical composition
  - Protein (db) 91%
  - Moisture 4%
  - Lactose 3%
  - Fat <1%
  - Ash 2%
- Characteristics
  - Color: cream to dark cream
  - Flavor: na
  - pH 6.5
- Storage
  - na

*Exact composition depends on manufacturer

Typical Product Labeling
Whey protein hydrolysate, Whey protein concentrate
**Lactalbumin**

Lactalbumin is produced by precipitating whey proteins. Heat and changes in pH may be used to denature the whey proteins so that they aggregate and separate from the other whey constituents.

Lactalbumin is different from $\alpha$-lactalbumin.

Proteins are not soluble because they have been denatured.

Although some products in the US are referred to as lactalbumin these products are different in composition and functionality than the product described here. Lactalbumin in this form is typically a European product and is not produced in the US.

Final product composition and functionality depends on:
- Temperature/holding time
- pH
- Whey type
- Calcium concentration
- Dryer used

**Regulations**
- None, product not defined

**Animal Feed Definition** (Association of Animal Feed Control Officials)
Dried Lactalbumin - is obtained from drying coagulated protein from whey. It contains a minimum of 80% crude protein on a moisture-free basis.
### General composition of lactalbumin

<table>
<thead>
<tr>
<th>Component</th>
<th>Lactalbumin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>85%</td>
</tr>
<tr>
<td>Lactose</td>
<td>6%</td>
</tr>
<tr>
<td>Ash</td>
<td>3%</td>
</tr>
<tr>
<td>Fat</td>
<td>2%</td>
</tr>
<tr>
<td>Moisture</td>
<td>4%</td>
</tr>
</tbody>
</table>

### General Process for Manufacture of Lactalbumin

1. **Whey**
2. pH adjustment
3. Heat treatment
4. Aggregated whey proteins
5. Separate
6. Deproteinated whey (lactose, minerals)
7. Aggregated whey proteins with impurities
8. Water
9. Wash/dewater
10. Water, lactose, minerals
11. Aggregated whey proteins
12. Dry
13. Water
14. Mill
15. Lactalbumin
**Manufacture of Lactalbumin**

- Wash/Dewater
- Water
- Dry
- Mill
- Lactalbumin

**Typical composition and characteristics**

**Lactalbumin**
- Typical composition
  - Protein (db): 89%
  - Moisture: 4%
  - Lactose: 5%
  - Fat: 2%
  - Ash: 3%

- Characteristics: not available
- Storage: not available
**Whey Protein Concentrate (WPC)**

Produced by a pressure driven process known as ultrafiltration (UF). Ultrafiltration uses semipermeable membranes to separate the components in whey.

Lactose and minerals are removed until the desired protein content is reached. Permeate is a by product of this process. Higher protein WPCs require the use of water, in a process known as diafiltration (DF), to remove greater amounts of lactose and ash.

Proteins are not denatured by the UF process therefore WPCs can be very soluble.

Sweet or acid whey may be used, however, WPCs typically are produced from sweet whey.

**Whey protein concentrates** (ADPI/CFR definition) - is the substance obtained by the removal of sufficient non-protein cibstutents from whey so that the finished dry product contains not less than 25% protein. Whey protein concentrate is produced by physical separation techniques such as precipitation, filtration or dialysis. The acidity of the whey protein concentrate may be adjusted by addition of safe and suitable pH adjusting ingredients.

**Regulations**
- 21 CFR 184.1979c

**ADPI Industry Standard**

**Animal Feed Definition** (Association of Animal Feed Control Officials)
Dried (Dry) Whey Protein Concentrate - is the product is obtained by removal or separation of water, lactose and/or minerals from whey by ultra-filtration, dehydration or other processes. It shall contain 25% minimum crude protein. The minimum percentage of crude protein and lactose and the maximum percentage of lactose must be prominently declared on the label.

**General composition of whey protein concentrates (WPC)**

<table>
<thead>
<tr>
<th>Component</th>
<th>WPC 34</th>
<th>WPC 55</th>
<th>WPC 80</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>33</td>
<td>53</td>
<td>77</td>
</tr>
<tr>
<td>Lactose</td>
<td>52</td>
<td>31</td>
<td>9</td>
</tr>
<tr>
<td>Ash</td>
<td>7</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Fat</td>
<td>4</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
### CFR specifications for whey protein concentrate (WPC)*

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>1</td>
<td>10</td>
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<tr>
<td>Protein</td>
<td>25</td>
<td>–</td>
</tr>
<tr>
<td>Lactose</td>
<td>–</td>
<td>60</td>
</tr>
<tr>
<td>Ash</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Moisture</td>
<td>1</td>
<td>6</td>
</tr>
</tbody>
</table>

* 21 CFR 184.1979

### ADPI industry standard for whey protein concentrate 34 (WPC 34)

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein*</td>
<td>34.0 - 36.0</td>
<td>33.5</td>
<td>–</td>
</tr>
<tr>
<td>Lactose</td>
<td>48.0 - 55.0</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Ash</td>
<td>6.5 - 8.0</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Fat</td>
<td>3.0 - 4.5</td>
<td>–</td>
<td>5</td>
</tr>
<tr>
<td>Moisture</td>
<td>3.0 - 5.0</td>
<td>–</td>
<td>6</td>
</tr>
</tbody>
</table>

*Protein is reported on a dry basis. All other components are reported "as is".

### ADPI industry standard for whey protein concentrate 80 (WPC 80)

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein*</td>
<td>80.0 - 82.0</td>
<td>79.5</td>
<td>–</td>
</tr>
<tr>
<td>Lactose</td>
<td>4.0 - 10.0</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Ash</td>
<td>6.5 - 5.0</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Fat</td>
<td>4.0 - 8.0</td>
<td>–</td>
<td>10</td>
</tr>
<tr>
<td>Moisture</td>
<td>3.5 - 5.0</td>
<td>–</td>
<td>6</td>
</tr>
</tbody>
</table>

*Protein is reported on a dry basis. All other components are reported "as is".
Manufacture of WPC 34 to 50

Manufacture of WPC 50 to 80

Typical composition and characteristics

WPC 34
- Typical composition
  - Protein (db): 34%
  - Moisture: 4%
  - Lactose: 52%
  - Fat: 4%
  - Ash: 7%
- Characteristics
  - Color: white to light cream
  - Flavor: bland, clean
  - pH: 6.0-6.7
- Storage
  - < 27 C, <65% rh
  - 9-12 months

WPC 55
- Typical composition
  - Protein (db): 55%
  - Moisture: 4%
  - Lactose: 31%
  - Fat: 6%
  - Ash: 6%
- Characteristics
  - Color: white to light cream
  - Flavor: bland, clean
  - pH: 6.0-6.7
- Storage
  - < 27 C, <65% rh
  - 9-12 months

WPC 80
- Typical composition
  - Protein (db): 80%
  - Moisture: 4%
  - Lactose: 9%
  - Fat: 6%
  - Ash: 4%
- Characteristics
  - Color: white to light cream
  - Flavor: bland, clean
  - pH: 6.0-6.7
- Storage
  - < 27 C, <65% rh
  - 9-12 months

Product Labeling
Whey Protein Concentrate (_____ % protein)

The percent of protein is declared in 5% increments OR as actual percentage provided an analysis of the product is supplied.
**Whey Protein Isolate (WPI)**

Whey protein concentrates with protein contents on a dry basis greater than 90% are referred to as whey protein isolates (WPI).

WPIs are produced by one of two methods:
- MF/UF
- Ion exchange

Protein composition of the WPI will depend on the method used. A significant difference is the presence of glycomacropeptide (GMP). GMP is a protein fragment resulting from the action of rennet on casein during cheesemaking. The ion exchange process does not capture GMP and therefore GMP is absent from WPI produced by ion exchange unless it is added back. MF/UF process retains GMP so that it is present in the resulting WPI.

Reports in the literature indicate the ratio of specific whey proteins also may differ between MF/UF and ion exchange produced WPIs. The producer of the specific WPI should be contacted for further information should the precise protein profile be important to the end user.

Whey protein isolate (ADPI definition) - is the substance produced by the removal of sufficient non-protein components from whey so that the finished dry product contains not less than 90% protein on a dry basis. Whey protein isolate is produced by separation techniques such as precipitation, membrane filtration and/or ion exchange. Whey protein isolate can be used as liquid or as a dry product. The acidity of whey protein isolate may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

**Types**

- Process used
  - MF/UF
  - Ion exchange
- Final form
  - Ordinary (non-agglomerated, non-instantized)
  - Instantized

**Regulations**

- FDA GRAS Notice No. 37 (2000)
- ADPI Industry Standard
General composition of whey protein isolate (WPI)

<table>
<thead>
<tr>
<th>Component</th>
<th>WPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>89</td>
</tr>
<tr>
<td>Lactose</td>
<td>2</td>
</tr>
<tr>
<td>Ash</td>
<td>3</td>
</tr>
<tr>
<td>Fat</td>
<td>1</td>
</tr>
<tr>
<td>Moisture</td>
<td>5</td>
</tr>
</tbody>
</table>

Whey protein isolate composition (WPI)

- **Fat**: 80%
- **Ash**: 60%
- **Lactose**: 40%
- **Protein**: 20%

FDA specifications for whey protein isolate (WPI)*

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than (WPI)</th>
<th>Not greater than (WPI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
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<tr>
<td>Protein</td>
<td>90</td>
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<tr>
<td>Lactose</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>Ash</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>6</td>
</tr>
</tbody>
</table>

* FDA GRAS Notice No. 37 (2000)

ADPI industry standard for whey protein isolate (WPI)

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein*</td>
<td>90.0 - 92.0</td>
<td>89.5</td>
<td>-</td>
</tr>
<tr>
<td>Lactose</td>
<td>0.5 - 1.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ash</td>
<td>2.0 - 3.0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Fat</td>
<td>0.5 - 1.0</td>
<td>-</td>
<td>1.5</td>
</tr>
<tr>
<td>Moisture</td>
<td>4.0 - 5.0</td>
<td>-</td>
<td>6.0</td>
</tr>
</tbody>
</table>

*Protein is reported on a dry basis. All other components are reported "as is".
General Process for the Manufacture of Whey Protein Isolate (WPI) by Membranes

1. **Whey**
2. **Microfiltration** → **Phospholipid and some protein**
3. **Ultrafiltration/Diafiltration** → **Permeate** (lactose, minerals)
4. **Retentate** (whey protein, some lactose/ash)
5. **Concentrate** → **Water**
6. **Spray Dry** → **Water**
7. **Whey Protein Isolate**

General Process for the Manufacture of Whey Protein Isolate (WPI) by Chromatography

1. **Whey**
2. **Ion Exchange** → **Deproteinated whey** (fat, lactose, minerals)
3. **Proteins and some minerals bound to beads**
4. **Caustic/acid solutions** → **Proteins/minerals released from beads** → **Spent caustic/acid solutions**
5. **Ultrafiltration/Diafiltration** → **Permeate** (minerals)
6. **Retentate** (whey protein, some lactose/ash)
7. **Concentrate** → **Water**
8. **Spray Dry** → **Water**
9. **Whey Protein Isolate**
Manufacture of Whey Protein Isolate (WPI)

Typical composition and characteristics

**Whey Protein Isolate (WPI)**
- **Typical composition**
  - Protein (db) 93%
  - Moisture 1%
  - Lactose 3%
  - Fat 1%
  - Ash 5%
- **Characteristics**
  - Color: white to cream
  - Flavor: bland, clean
- **Storage**
  - < 27 C, <65% rh
  - 12 months

**Whey Protein Isolate (WPI) - Instantized**
- **Typical composition**
  - Protein (db) 93%
  - Moisture 5%
  - Lactose 3%
  - Fat 1%
  - Ash 2%
- **Characteristics**
  - Color: off white to cream
  - Flavor: bland, clean
- **Storage**
  - < 27 C, <65% rh
  - 12 months

* Composition does not include soy lecithin (<1.5%) added to instantized product.

**Product Labeling**

Whey Protein Isolate ( _____ % protein)

The percent of protein is declared in 2% increments OR as actual percentage provided an analysis of the product is supplied.
Heat Stable Whey Protein Concentrate

Heat stable whey protein concentrates have increased tolerance to temperatures that would lead to denaturation/floculation of whey proteins. The method used to achieve increased stability often is a proprietary process. Whey protein concentrates modified for heat stability typically have a protein content between 34 and 80%.

General approaches to increased heat stability:
• Addition of phosphate salts
• Protein hydrolysis

Phosphate salts limit the ability of whey proteins to interact and floculate by chelating calcium and increasing pH. Hydrolysis of whey proteins results in protein fragments that are too small to appear as floc.

Regulations
• None, product not defined

Heat stable whey protein concentrate composition

<table>
<thead>
<tr>
<th>Component</th>
<th>Heat stable WPC34</th>
<th>Heat stable WPC80</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>34</td>
<td>77</td>
</tr>
<tr>
<td>Lactose</td>
<td>51</td>
<td>8</td>
</tr>
<tr>
<td>Ash</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Fat</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

General Process for the Manufacture of Heat Stable Whey Protein Concentrate

Whey → Ultrafiltration → Diafiltration → Permeate (lactose, ash)

Whey → Enzymes/phosphates → Retentate (whey protein, fat, some lactose/ash)

Whey → Spray Dry → Concentrate

Whey → Water
Manufacture of Heat Stable Whey Protein Concentrate

Typical composition and characteristics

**Heat stable WPC34***
- Typical composition:
  - Protein (db): 35%
  - Moisture: 4%
  - Lactose: 51%
  - Fat: 4%
  - Ash: 7%

- Characteristics:
  - Color: cream
  - Flavor: typical dairy
  - pH: 6.9

- Storage:
  - <27°C, <65% rh
  - 18 months

**Heat stable WPC80***
- Typical composition:
  - Protein (db): 81%
  - Moisture: 4%
  - Lactose: 7%
  - Fat: 5%
  - Ash: 6%

- Characteristics:
  - Color: cream
  - Flavor: typical dairy
  - pH: 6.8

- Storage:
  - <27°C, <75% rh

*Exact composition depends on manufacturer*
Whey Protein Phospholipid Concentrate (WPPC)

Whey protein phospholipid concentrates (WPPC) are a relatively new dairy ingredient and are not defined. They also are known as procream, reduced lactose concentrated whey and concentrated whey protein.

Whey protein phospholipid concentrates are a co-product of WPI production. Producing WPI by ultrafiltration requires an additional fat removal step since the amount of residual fat in whey would limit the possible protein content of the WPI to less than 90%. One method of fat removal is microfiltration. The MF process retains the undesired residual fat with the resulting permeate continuing on for manufacture into WPI. Some of the protein in the whey is retained along with the residual fat. It is this mixture of fat and protein that is known as whey protein phospholipid concentrate. The ratio of protein to fat will vary depending on the conditions used during microfiltration.

Proteins are not denatured by either UF or MF, therefore, the proteins remain soluble. The composition of the fat will more closely resemble the composition of whey cream as compared to the fat profile found in milk.

Whey protein phospholipid concentrate (ADPI definition) - is a product obtained through microfiltration of whey which concentrates whey proteins and whey phospholipids. The acidity of WPPC may be adjusted by addition of safe and suitable pH-adjusting ingredients.

**Regulations**
- None, product not defined

**ADPI Industry Standard**

<table>
<thead>
<tr>
<th>Component</th>
<th>WPPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>60</td>
</tr>
<tr>
<td>Lactose</td>
<td>11</td>
</tr>
<tr>
<td>Ash</td>
<td>5</td>
</tr>
<tr>
<td>Fat</td>
<td>20</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
</tr>
</tbody>
</table>
ADPI industry standard for whey protein phospholipid concentrate (WPPC)

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein*</td>
<td>na</td>
<td>50</td>
<td>-</td>
</tr>
<tr>
<td>Lactose</td>
<td>na</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ash</td>
<td>na</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>Fat</td>
<td>na</td>
<td>-</td>
<td>8</td>
</tr>
<tr>
<td>Moisture</td>
<td>na</td>
<td>-</td>
<td>6</td>
</tr>
</tbody>
</table>

*Protein is reported on a dry basis. All other components are reported "as is".

General Process for the Manufacture of Whey Protein Phospholipid Concentrate (WPPC)

1. Whey
2. Microfiltration
3. Retentate (Phospholipid with some protein, lactose and minerals)
4. Concentrate
5. Spray Dry
6. Whey Protein Phospholipid Concentrate
**Manufacture of Whey Protein Phospholipid Concentrate (WPPC)**

- Pasteurized Fluid Whey
- Microfiltration
- Concentrate/Spray Dry
- Whey Protein Phospholipid Concentrate
- WPI for further processing

**Typical composition and characteristics**

**WPPC***

- **Typical composition**
  - Protein (db): 62%
  - Moisture: 4%
  - Lactose: 11%
  - Fat: 20%
  - Ash: 5%

- **Characteristics**
  - Color: light cream
  - Flavor: clean, slightly sweet

- **Storage**
  - <25 C, <65% rh
  - 12 months

*Exact composition depends on manufacturer

**Product Labeling**

It is recommended that the product be labeled as "Whey Protein Phospholipid Concentrate".

An alternate name could be High Fat Whey Protein Concentrate.
Alpha-Lactalbumin Enriched Whey Protein Concentrate

Alpha-lactalbumin enriched whey protein concentrate is a relatively new dairy ingredient and is not defined. The product is produced by a patented process that typically involves the use of membrane processes such as UF/MF. Proteins are not denatured by the UF/MF process, therefore, the proteins remain soluble.

Alpha-lactalbumin enriched whey protein concentrate has a higher concentration of alpha-lactalbumin as compared to beta-lactoglobulin (the other major protein in whey). The product is said to have high heat stability and solubility.

Regulations
◆ None, product not defined

General composition of alpha-lactalbumin enriched whey protein concentrate

<table>
<thead>
<tr>
<th>Component</th>
<th>Alpha-Lactalbumin enriched</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>79</td>
</tr>
<tr>
<td>Lactose</td>
<td>2</td>
</tr>
<tr>
<td>Ash</td>
<td>3</td>
</tr>
<tr>
<td>Fat</td>
<td>12</td>
</tr>
<tr>
<td>Moisture</td>
<td>4</td>
</tr>
</tbody>
</table>

General Process for the Manufacture of Alpha-Lactalbumin Enriched Whey Protein Concentrate
Manufacture of Alpha-Lactalbumin Enriched Whey Protein Concentrate

Typical composition and characteristics

Alpha-Lactalbumin Enriched Whey Protein Concentrate

- **Typical composition**
  - Protein (db) 81%
  - α-lactalbumin** 30%
  - β-lactoglobulin** 18%
  - Moisture 4%
  - Lactose 1%
  - Fat 12%
  - Ash 3%

- **Characteristics**
  - Color: light cream
  - Flavor: bland

- **Storage**
  - <25°C, <75% rh
  - 24 months

*Exact composition depends on manufacturer

**As is basis

Typical ratio of α-lactalbumin to β-lactoglobulin 27:73

Enriched ratio of α-lactalbumin to β-lactoglobulin 62:38
Individual Whey Proteins

Individual proteins are produced by ion exchange/chromatographic methods. The desired protein typically is captured on special “beads” or membranes while the remainder of the whey proteins proceeds unhindered through the vessel. Special solutions are then used to release the captured proteins. The desired proteins typically have a very high purity especially as compared to enriched products that have increased concentrations of a particular protein or group of proteins.

α-Lactalbumin – makes up approximately 20 – 25% of the whey proteins. Denatures at 144°F (62°C). Binds calcium which stabilizes it against denaturation.

Lactoferrin - is an iron binding protein. Present at 30 – 100 mg/L in whey. Lactoferrin is not denatured by standard pasteurization (72°C for 15 seconds).

Lactoperoxidase – is an enzyme with antimicrobial ability. It is present in whey at approximately 1 – 30 mg/L and is considered to be relatively heat resistant.

Glycomacropeptide (GMP) – is a peptide that is also known as casein macropeptide (CMP). The peptide is formed when rennet clips off a piece of κ-casein during cheese manufacture. GMP therefore is present only in whey that is produced using rennet.

Types
- α-Lactalbumin
- Lactoferrin
- Lactoperoxidase
- Glycomacropeptide (GMP)

Regulations
- Lactoferrin
  - FDA GRAS Notice No. 42 (2001)
- Other proteins
  - None, products not defined

Individual whey protein composition

<table>
<thead>
<tr>
<th>Percentage of total solids (%)</th>
<th>Whey</th>
<th>α-lactalbumin</th>
<th>Lactoferrin</th>
<th>GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ash</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### General composition of individual whey proteins

<table>
<thead>
<tr>
<th>Component</th>
<th>α-Lactalbumin</th>
<th>Lactoferrin</th>
<th>Lactoperoxidase</th>
<th>GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>90</td>
<td>94</td>
<td>92</td>
<td>86</td>
</tr>
<tr>
<td>Lactose</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Ash</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Fat</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Moisture</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

### General Process for the Manufacture of Individual Whey Proteins

1. **Whey**
2. **Ultrafiltration/diafiltration**
3. **Desired proteins and some minerals bound to beads**
4. **Spent caustic/acid solutions**
5. **Whey with undesired proteins, fat, lactose, minerals**
6. **Water**
7. **Concentrate**
8. **Spray dry**
9. **Specific Proteins**
10. **Ultrafiltration/diafiltration**
11. **Retentate (whey protein, some lactose/ash)**
12. **Caustic/acid solutions**
13. **Proteins/minerals released from beads**
14. **Desired proteins and some minerals bound to beads**
15. **Whey with undesired proteins, fat, lactose, minerals**
16. **Water**
17. **Concentrate**
18. **Spray dry**
19. **Specific Proteins**
Manufacture of Individual Whey Proteins

Typical composition and characteristics

α-Lactalbumin
- Typical composition:
  - Protein (db): 98%
  - Lactalbumin*: 91%
  - Moisture: 5%
  - Lactose: 1%
  - Fat: 1%
  - Ash: 3%
- Characteristics:
  - Color: light cream
  - Flavor: bland, clean
  - pH: 7
  - Solubility: fully soluble
- Storage:
  - < 27 C, <65% rh
  - 12 months

Lactoferrin
- Typical composition:
  - Protein (db): 99%
  - Lactoferrin*: 96%
  - Moisture: 5%
  - Lactose: na
  - Fat: na
  - Ash: 1%
- Characteristics:
  - Color: light red
  - Flavor: na
  - pH: 6-7
  - Solubility: 99%
- Storage:
  - < 25 C, <65% rh
  - time period: na

Lactoperoxidase
- Typical composition:
  - Protein (db): 97%
  - Lactoperoxidase*: na%
  - Moisture: 5%
  - Lactose: na
  - Fat: na
  - Ash: 3%
- Characteristics:
  - Color: green/brown
  - Flavor: na
  - pH: 7
  - Solubility: fully soluble
- Storage:
  - 2-8 C, na rh
  - 6 months

Glycomacropeptide (GMP)
- Typical composition:
  - Protein (db): 92%
  - GMP*: 96%
  - Moisture: 6%
  - Lactose: 1%
  - Fat: 1%
  - Ash: 6%
- Characteristics:
  - Color: light cream
  - Flavor: bland, clean
  - pH: na
  - Solubility: na
- Storage:
  - < 27 C, <65% rh
  - 12 months

* Given as a percentage of total protein
Permeate (Whey)

Permeate is a by product of whey protein concentrate (WPC), whey protein isolate (WPI), milk protein concentrate (MPC) or milk protein isolate (MPI) production. Permeate actually is a term used to cover a family of products that have a minimum of 59% lactose, and a maximum of 10% protein and 27% ash. Manufacturers in the United States use the terms “dairy product solids”, “de-proteinized whey”, “modified whey”, “reduced protein whey” or “permeate” on the label.

Milk and sweet, acid, casein and rennet wheys may be used as starting materials. Composition of permeate will vary somewhat depending on the original material used. Sweet whey and milk are the most common starting materials for permeate production in the United States.

Permeate may contain a maximum of 10% protein according to product definition. Permeate typically has only trace amounts of protein, however, commercial specifications often list protein at 3.5 to 5%. The discrepancy is due to the method used to test for protein. The industry tests for total nitrogen and then multiplies the result by 6.38 to convert the result into a protein value. The nitrogen found by testing often actually is nonprotein nitrogen (NPN) rather than true protein. Examples of NPN compounds typically found in milk and whey include: urea; creatine; creatinine; uric acid; orotic acid; and ammonia. The net result of listing nitrogen as protein rather than NPN is an overestimation of the protein and underestimation of the lactose content of the powder. It should be noted that there are manufacturers of permeate who add protein to permeate to assist with drying.

Dairy Product Solids (ADPI definition) - are modified dairy products (permeates and products derived therefrom) obtained by the removal of protein and/or lactose, and/or minerals from milk or whey. The dry product shall contain at least 59% lactose, 10% protein maximum, and 27% ash maximum. Removal of the dairy constituents is accomplished by separation techniques such as precipitation, membrane filtration or dialysis. Dairy Product Solids can be used as a liquid or as a dry product. The acidity of dairy product solids may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

Dairy permeate (ADPI definition) - produced by the removal of protein and other solids from milk or whey resulting in a product with a high concentration of lactose. Removal of the dairy constituents is accomplished by physical separation techniques such as filtration and diafiltration. The acidity of Dairy Permeate may be adjusted by the addition of safe and suitable pH adjusting ingredients. Dairy Permeate meets the definition of Dairy Product Solids, which is the subject of a GRAS notification to the U.S. Food and Drug Administration and complies with all provisions of the U.S. Federal Food, Drug and Cosmetic Act.

Types
♦ Milk
♦ Whey

Regulations
♦ FDA GRAS Notice No. 37 (2000)
♦ FDA GRP 1G0371

ADPI Industry Standard

Animal Feed Definition (Association of American Feed Control Officials)
Dried (dry) whey solubles - is the product obtained by drying the whey residue after removal of whey protein, with or without partial removal of lactose. Minimum percent of crude protein and lactose and maximum percent ash must be prominently declared on the label.
Permeate composition

General composition of permeate from several sources

<table>
<thead>
<tr>
<th>Component</th>
<th>Permeate from</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Milk</td>
</tr>
<tr>
<td>Total solids</td>
<td>5.8%</td>
</tr>
<tr>
<td>Lactose</td>
<td>4.9%</td>
</tr>
<tr>
<td>Ash</td>
<td>0.45%</td>
</tr>
<tr>
<td>Crude protein</td>
<td>0.25%</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>---</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Permeate from</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Milk</td>
</tr>
<tr>
<td>Calcium</td>
<td>28</td>
</tr>
<tr>
<td>Phosphorous</td>
<td>33</td>
</tr>
</tbody>
</table>

General composition of permeate

<table>
<thead>
<tr>
<th>Component</th>
<th>Permeate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein*</td>
<td>3%</td>
</tr>
<tr>
<td>Lactose</td>
<td>84%</td>
</tr>
<tr>
<td>Ash</td>
<td>9%</td>
</tr>
<tr>
<td>Fat</td>
<td>nil</td>
</tr>
<tr>
<td>Moisture</td>
<td>4%</td>
</tr>
</tbody>
</table>

* Non protein nitrogen included in this value. May or may not contain true protein.
FDA specifications for permeate *

<table>
<thead>
<tr>
<th>Component</th>
<th>Not less than</th>
<th>Not greater than</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Protein</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>Lactose</td>
<td>59</td>
<td>-</td>
</tr>
<tr>
<td>Ash</td>
<td>-</td>
<td>27</td>
</tr>
<tr>
<td>Moisture</td>
<td>-</td>
<td>6</td>
</tr>
</tbody>
</table>

* FDA GRAS Notice No. 37 (2000) and FDA GRP No. 1G0371

ADPI industry standard for whey permeate

<table>
<thead>
<tr>
<th>Component</th>
<th>Typical</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>2 - 7</td>
<td>-</td>
<td>7</td>
</tr>
<tr>
<td>Lactose</td>
<td>76 - 85</td>
<td>76</td>
<td>-</td>
</tr>
<tr>
<td>Ash</td>
<td>8 - 11</td>
<td>76</td>
<td>14</td>
</tr>
<tr>
<td>Fat</td>
<td>0 - 1.0</td>
<td>-</td>
<td>1.5</td>
</tr>
<tr>
<td>Moisture</td>
<td>3 - 4.5</td>
<td>-</td>
<td>5</td>
</tr>
</tbody>
</table>

General Process for the Manufacture of Whey Permeate

1. **Whey**
2. **Ultrafiltration/diafiltration**
   - Retentate (whey proteins, some lactose/ash)
3. **Evaporate**
4. **Crystallize**
5. **Dry**
6. **Package**
7. **Whey Permeate**
Manufacture of Permeate from Whey

Permeate
- Typical composition
  - Protein (db) 3%
  - Moisture 4%
  - Lactose 85%
  - Fat < 0.1%
  - Ash 9%
- Characteristics
  - Color: white to cream
  - Flavor: bland, clean
  - Storage < 25 C, <65% rh
  - 12 months

Typical composition and characteristics

* Non protein nitrogen included in this value. May or may not contain true protein.

Product Labeling
Product may be identified on the label as "Whey Permeate" or "Dairy Product Solids".

An alternate names could include "Modified Whey", "Deproteinized Whey", "Dried Whey Product" or "Dried Whey Solubles".
**Galacto-Oligosaccharides (GOS)**

Galacto-oligosaccharides (GOS) are comprised of galactose units chained together. Galacto-oligosaccharides are naturally occurring in milk and yogurt and function as prebiotics, that is, they are undigestible ingredients that stimulate the growth/activity of beneficial bacteria in the colon.

Galacto-oligosaccharides are produced when enzymes alter lactose. The type of GOS produced depends on factors such as enzyme source and amount, initial lactose concentration, whether the enzyme is free or immobilized, reaction conditions and composition of the starting material.

Commercial products differ in the purity of the GOS and the exact configuration of the compounds. Galacto-oligosaccharides are available in both liquid and dry forms. Liquid products typically contain about 50% w/v of GOS and powders 60 - 70%.

**Regulations**

None, product not defined

FDAGRASTable 1: General composition of galacto-oligosaccharides (GOS)

<table>
<thead>
<tr>
<th>Component</th>
<th>GOS #1</th>
<th>GOS #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milkfat</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Protein</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Lactose and simple sugars</td>
<td>43</td>
<td>27</td>
</tr>
<tr>
<td>Galacto-oligosaccharides</td>
<td>54</td>
<td>70</td>
</tr>
<tr>
<td>Ash</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Moisture</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

**General Process for the Manufacture of Galacto-Oligosaccharides (GOS)**

1. **Lactose/Permeate**
2. **Water**
3. **Dissolve powder**
4. **Enzymes**
5. **Lactose with dissolved impurities (minerals, NPN)**
6. **Inactivate enzymes**
7. **Filter**
8. **Minerals, some lactose/monosaccharides**
9. **Dry**
10. **Galacto-Oligosaccharides (GOS)**
11. **Water**
12. **Package**

---

**Galacto-oligosaccharide (GOS) composition**

<table>
<thead>
<tr>
<th>Component</th>
<th>GOS #1</th>
<th>GOS #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Manufacture of Galacto-Oligosaccharides (GOS)

Typical composition and characteristics

**GOS #1***
- Typical composition
  - Protein (db) na%
  - Moisture 3%
  - Lactose and simple sugars (db) 45%
  - GOS (db) 55%
  - Fat <0.1%
  - Ash <0.1%
- Characteristics
  - Color: white
  - Flavor: sweet
  - pH na
- Storage
  - <36 C, <65% rh
  - 24 months

**GOS #2***
- Typical composition
  - Protein (db) na%
  - Moisture 3%
  - Lactose and simple sugars (db) 30%
  - GOS (db) 70%
  - Fat na%
  - Ash <0.1%
- Characteristics
  - Color: white
  - Flavor: sweet
  - pH na
- Storage
  - na

* Exact composition depends on manufacturer
Lactose

Lactose can be produced from either whey or permeate although permeate is the more common starting material. Whey or permeate is concentrated until the solubility of lactose is exceeded and lactose crystals form. The crystals then are washed to remove impurities and dried.

Lactose is a disaccharide, that is, a carbohydrate made up of two sugar molecules. The monosaccharides or sugar molecules that comprise lactose are glucose and galactose. The chemical name for lactose is 4-O-β-galactopyranosyl-D-glucopyranose.

Lactose crystals
Although lactose can exist in a number of different forms, when dried it typically is present as:
- Alpha-lactose monohydrate crystals
- Beta-lactose crystals
- Amorphous (glass) mixture of uncrystallized alpha (α) and beta (β) lactose

Alpha-lactose monohydrate crystals – formed when lactose crystallizes at temperatures <93.5°C (200°F). The α-lactose monohydrate form has one molecule of water as part of its structure. The molecule of water is bound to the lactose crystal and is also known as the water of crystallization. Alpha-lactose crystals often appear as prisms or tomahawk shapes. The crystals are very hard and can have a “sandy” or even glass-like mouthfeel.

Beta-lactose crystals – formed when lactose crystallizes at temperatures >93.5°C (200°F). The β form does not have water associated with its structure.

Amorphous (glass) – formed when a lactose solution is dried rapidly such as by spray drying or freeze drying. The amorphous form is very hygroscopic and will readily absorb water to form α–lactose monohydrate crystals. Lumps can develop in the product if enough crystals form. The amorphous form is typical in products such as nonfat dry milk.

Several other forms of lactose can be produced under special conditions.

Stable anhydrous α-lactose – produced at temperatures between 100 and 190°C (212 and 374°F) with a water vapor pressure of 6 to 80 cm mercury. Typically crystallized α-lactose monohydrate is sprayed onto a drum dryer to produce stable anhydrous α-lactose. Stable anhydrous α-lactose is relatively nonhygroscopic.

Hygroscopic (unstable) anhydrous α-lactose – is produced by heating α-hydrate lactose at temperatures above 100°C (212°F) under vacuum. Hygroscopic (unstable) anhydrous α-lactose is stable in dry air but will readily absorb moisture under typical atmospheric conditions.

Lactose and water
Lactose as a commercial product typically is in the form of α-lactose monohydrate. Beta-lactose was produced many years ago but is not typically available commercially except in the form of anhydrous lactose. Mixtures of α-lactose and β-lactose also are available.

Moisture specifications reflect the fact that water can be present in two different forms in lactose.

Bound – water that is part of the crystal structure of α-lactose.
Free – water that is not associated with the lactose crystal.
Total moisture – free and bound water.
The molecular weight of lactose is 342. The molecular weight of water is 18. Added together the molecular weight of $\alpha$-lactose monohydrate crystal becomes 360. Therefore there is 5% moisture in an $\alpha$-lactose monohydrate crystal due to bound water.

\[
\text{Lactose + water} = \alpha\text{-lactose monohydrate crystal} \\
342 \quad + \quad 18 \quad = \quad 360 \\
95\% \quad + \quad 5\% \quad = \quad 100\%
\]

The calculation for moisture in commercial lactose is based on the assumption that 100% of the lactose present is in the form of $\alpha$-lactose monohydrate. In many cases this is a good assumption, however, in certain lactose products where significant amounts of $\beta$-lactose, stable anhydrous $\alpha$-lactose or amorphous lactose may be present the assumption can lead to an underestimation of the free moisture content depending on the method of moisture analysis used. Free moisture content is important because it has a large affect on product shelf life.

Loss on drying refers to the free moisture content of lactose. The greater the loss on drying the more free moisture is present.

The Karl Fischer test for moisture indicates both bound and free moisture in lactose.

Free moisture must be less than 1% according to standards of identity. Because a free moisture of more than 1% would lead to quality issues, free moisture in crystalline lactose typically is less than 0.5%. The type of lactose affects the amount of free moisture typically present. Spray dried lactose would have a free moisture of not more than 1% while anhydrous lactose would have a free moisture of not more than 0.5%.

An example of moisture in lactose would be:

<table>
<thead>
<tr>
<th>Bound</th>
<th>Free</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>0.3%</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

### Commercial lactose products

**Industrial, fermentation lactose** is not defined. The product essentially is lactose that does not meet the specifications for edible (food) or pharmaceutical lactose.

**Edible (food) lactose** is produced by evaporating, crystallizing, refining and then drying. The majority of lactose is dried on a flash dryer although spray and roller dryers also may be used. Only the lactose crystals are dried.

Although the product consists of primarily of $\alpha$-lactose monohydrate some lactose will be in the amorphous form. The exact ratios of $\alpha$-lactose monohydrate to amorphous lactose depend on the method of production; however, it is possible that 3 to 5% of the lactose is in the amorphous form. Typically more than 90% of the lactose is in the $\alpha$-monohydrate form.

**Edible refined sprayed dried lactose** is not defined but lies between edible and pharmaceutical lactose in composition and functionality. The product is produced by evaporating, crystallizing, refining, re-evaporating, re-crystallizing and then spray drying. The lactose crystals and the mother liquor (the liquid from which the lactose crystallizes) are sprayed dried together. Edible refined lactose is a mixture of $\alpha$-lactose monohydrate and amorphous lactose.

**Pharmaceutical lactose** is produced by redissolving, refining and then filtering edible lactose crystals. The lactose then is evaporated, recrystallized and dried. There are three forms of pharmaceutical lactose: spray dried; crystalline; and anhydrous. The anhydrous type is drum (roller) dried and is primarily $\beta$-lactose.

Lactose also may be known as milk sugar.

### Regulations

- **Industrial, fermentation**
  - None, product not defined
- **Edible (Food)**
  - 21 CFR 168.122
  - Food Chemical Codex (FCC)
- **Edible refined**
  - None, product not defined
- **Pharmaceutical**
  - National Formulary (NF)
**Lactose Definitions**

**Lactose (CFR)** – the carbohydrate normally obtained from whey. It may be anhydrous or contain one molecule of water of crystallization or be a mixture of both forms.

**Lactose (FCC)** – occurs as a white to creamy white, crystalline powder. It is normally obtained from whey. It may be anhydrous, contain one molecule of water of hydration, or contain a mixture of both forms if it has been prepared by a spray-drying process.

**Anhydrous lactose (NF)** – is primarily β-lactose or a mixture of α- and β-lactose.

**Lactose monohydrate (NF)** – is a natural disaccharide obtained from milk, which consists of one glucose and one galactose moiety. (Note – lactose monohydrate may be modified as to its physical characteristics. It may contain varying proportions of amorphous lactose.)

**Lactose (Milk Sugar)** (ADPI definition) - is a white to creamy white crystalline product, possessing a mildly sweet taste. It may be anhydrous, contain one molecule of water hydration, or be a mixture of both forms. It is manufactured from whey or permeate by evaporating, crystallizing, refining and then drying the lactose crystals. Lactose for human consumption complies with all provisions of the U.S. Federal Food, Drug, and Cosmetic Act.

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**Lactose composition**

<table>
<thead>
<tr>
<th>Component</th>
<th>Industrial/fermentation</th>
<th>Edible (food)</th>
<th>Edible refined</th>
<th>Pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total protein</td>
<td>1.0</td>
<td>&lt; 0.10</td>
<td>nil</td>
<td>nil</td>
</tr>
<tr>
<td>Lactose</td>
<td>98.0</td>
<td>99.0</td>
<td>99.5</td>
<td>99.85</td>
</tr>
<tr>
<td>Ash</td>
<td>0.45</td>
<td>0.20</td>
<td>0.20</td>
<td>0.03</td>
</tr>
<tr>
<td>Fat</td>
<td>0.20</td>
<td>&lt; 0.10</td>
<td>nil</td>
<td>0.0</td>
</tr>
<tr>
<td>Moisture (free)</td>
<td>0.35</td>
<td>0.50</td>
<td>0.30</td>
<td>0.10</td>
</tr>
</tbody>
</table>
## Specifications for US food grade lactose

<table>
<thead>
<tr>
<th>Component</th>
<th>CFR</th>
<th>FCC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not less than</td>
<td>not greater than</td>
</tr>
<tr>
<td>Lactose (db)</td>
<td>98.0%</td>
<td>-</td>
</tr>
<tr>
<td>Sulfated ash (db)</td>
<td>-</td>
<td>0.3%</td>
</tr>
<tr>
<td>Ash</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total moisture</td>
<td>-</td>
<td>6.0%</td>
</tr>
<tr>
<td>Monohydrate</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Spray dried</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Anhydrous</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>pH (10% solution)</td>
<td>4.5</td>
<td>7.5</td>
</tr>
</tbody>
</table>

## General Process for the Manufacture of Food Grade Lactose

1. **Whey**
   - Ultrafiltration/diafiltration
   - Permeate (lactose, ash)
   - Retentate (whey proteins, some lactose/ash)
   - Evaporate
2. **Water**
3. **Lactose crystals with dissolved impurities (minerals, NPN)**
4. **Liquid fraction (uncrystallized lactose, minerals, NPN)**
5. **Wash water (uncrystallized lactose, minerals, NPN)**
6. **Delactosed permeate**
7. **Dry**
8. **Purified lactose crystals**
9. **Refine**
10. **Water**
11. **Lactose**

## General ADPI industry standards for lactose

<table>
<thead>
<tr>
<th>Component</th>
<th>Industrial/fermentation</th>
<th>Edible (food)</th>
<th>Edible refined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total protein (maximum)</td>
<td>1.0</td>
<td>0.20</td>
<td>0.15</td>
</tr>
<tr>
<td>Lactose (minimum)</td>
<td>98.0</td>
<td>99.0</td>
<td>99.5</td>
</tr>
<tr>
<td>Ash (maximum)</td>
<td>0.45</td>
<td>0.30</td>
<td>0.20</td>
</tr>
<tr>
<td>Moisture (total) (maximum)</td>
<td>6.0</td>
<td>6.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

## Common mesh sizes for edible lactose

<table>
<thead>
<tr>
<th>Mesh size</th>
<th>Sieve size</th>
<th>Minimum % passage through sieve</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 mesh</td>
<td>40</td>
<td>80</td>
</tr>
<tr>
<td>100 mesh</td>
<td>100</td>
<td>80</td>
</tr>
<tr>
<td>200 mesh</td>
<td>200</td>
<td>80</td>
</tr>
</tbody>
</table>
Manufacture of Edible Lactose

Typical composition and characteristics

**Edible (food) lactose**
- **Typical composition**
  - Protein* 0.2%
  - Moisture
    - total 4.6%
    - free 0.5%
  - Lactose** 99.0%
  - Fat na
  - Ash 0.3%
- **Characteristics**
  - Color: white to slight yellow
  - Flavor: clean, slight sweet
  - pH: 4.5 to 7.0
- **Storage**
  - < 25 C, <75% rh
  - 24 months

* Non protein nitrogen included in this value. May or may not contain true protein.

** Monohydrate

**Product Labeling**
Product may be identified on the label as "Lactose" or "Milk Sugar"
Specifications for US pharmaceutical lactose*

<table>
<thead>
<tr>
<th>Component</th>
<th>Monohydrate</th>
<th>Anhydrous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion and light absorbing impurities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>210 nm</td>
<td>- 0.25 au</td>
<td>- 0.25 au</td>
</tr>
<tr>
<td>300 nm</td>
<td>0.07 au</td>
<td>0.07 au</td>
</tr>
<tr>
<td>Ash</td>
<td>- 0.1%</td>
<td>- 0.1%</td>
</tr>
<tr>
<td>Total moisture</td>
<td>4.5%</td>
<td>5.5%</td>
</tr>
<tr>
<td>Free moisture</td>
<td>- 0.5%**</td>
<td>- 0.5%</td>
</tr>
<tr>
<td>Acidity (0.1N NaOH)</td>
<td>- 0.4 ml</td>
<td>- 0.4 ml</td>
</tr>
</tbody>
</table>

* National Formulary  
** Modified monohydrate not greater than 1.0%  
(Spray dried monohydrate)
General Process for the Manufacture of Pharmaceutical Grade Lactose

1. **Whey**
   - Ultrafiltration/diafiltration
     - Retentate (whey proteins, some lactose/ash)
     - Permeate (lactose, ash)
       - Evaporate
         - Water
       - Crystallize
       - Decant
       - Lactose crystals with dissolved impurities (minerals, NPN)
       - Liquid fraction (uncrystallized lactose, minerals, NPN)
     - Wash water (uncrystallized lactose, minerals, NPN)
     - Refine
       - Purified lactose crystals
       - Dry
       - Lactose
   - Water
   - Refine
     - Purified lactose crystals
     - Dry
     - Lactose

2. **Water**
   - Ultrafiltration/diafiltration
     - Permeate (lactose, ash)
       - Evaporate
         - Water
       - Crystallize
       - Decant
       - Lactose crystals with dissolved impurities (minerals, NPN)
       - Liquid fraction (uncrystallized lactose, minerals, NPN)
     - Wash water (uncrystallized lactose, minerals, NPN)
     - Refine
       - Purified lactose crystals
       - Dry
       - Lactose
   - Water
   - Refine
     - Purified lactose crystals
     - Dry
     - Lactose

3. **Lactose crystals**
   - Dissolved lactose
     - Activated carbon/Filter
       - Residue (color, carbon)
       - Evaporate
       - Recrystallize
       - Minerals
   - Liquid fraction (uncrystallized lactose, minerals, NPN)
   - Water
   - Roller dry
     - Anhydrous lactose
     - Purified lactose crystals
     - Flash dry
       - Water
       - Oversized crystals
       - Mill/Sift
       - Package
       - NF Lactose Monohydrate
     - NF Lactose Monohydrate, Modified Spray Dried
     - Package
     - Oversized crystals
     - NF Lactose Monohydrate
Manufacture of Pharmaceutical Lactose

Typical composition and characteristics

**Refined edible lactose (spray dried)**
- **Typical composition**
  - Protein*: nil
  - Moisture:
    - total: 5.0%
    - free: 0.3%
  - Lactose**: 99.5%
  - Fat: nil
  - Ash: 0.2%

- **Characteristics**
  - Color: white
  - Flavor: clean, slight sweet
  - pH 4.5 to 7.0

- **Storage**
  - < 25 C, <75% rh
  - 24 months

* Non protein nitrogen included in this value. May or may not contain true protein.
** May be combination of α-monohydrate and amorphous

**Pharmaceutical lactose (monohydrate)**
- **Typical composition**
  - Protein:
    - * Non protein nitrogen included in this value. May or may not contain true protein.
  - Moisture:
    - total: 5.0%
    - free: 0.3%
  - Lactose**: 99.5%
  - Fat:
  - Ash: 0.2%

- **Characteristics**
  - Color: white
  - Flavor: bland, slight sweet

- **Storage**
  - < 25 C, <75% rh
  - 36 months
Dairy Minerals

Dairy minerals may be produced from either whey or permeate. There are several methods for producing dairy minerals; however, generally the whey or permeate is concentrated such that calcium phosphate precipitates. The precipitated calcium phosphate then is removed from the liquid and washed to remove impurities such as lactose and nonprotein nitrogen. The resulting product typically has at least 20% calcium along with other minerals found in milk or whey.

The ratio of calcium to phosphorous or phosphate in dairy minerals is considered important by many end users. Typically a ratio similar to the ratio of calcium to phosphorous in milk is desired. Care must be taken when considering the ratio as some manufacturers express the ratio as calcium (Ca)/phosphorous (P) while other use calcium (Ca)/phosphate (PO₄). A typical ratio for calcium to phosphorous would be 1.8. A ratio of 0.6 would be typical for calcium to phosphate.

Calcium in whey typically is present in the form of calcium phosphate. Other minerals also are present and depending on their concentration they are divided into major and minor elements.

Major elements – calcium (Ca), sodium (Na), potassium (K), magnesium (Mg), chloride (Cl) and phosphorous (P)

Minor elements – zinc (Zn), copper (Cu), iron (Fe) and others

The terms minerals, salts and ash often are used interchangeably; however, they are not equivalent terms.

Minerals – generally refers to elements other than carbon (C), hydrogen (H), oxygen (O) and nitrogen (N) that are found in dairy products.

Minerals typical in dairy products include calcium (Ca), magnesium (Mg), phosphorous (P), iron (Fe), potassium (K), sodium (Na) and zinc (Zn).

Milk salts – includes both inorganic and organic substances. Organic acids with a negative charge and amino acids with positive charges are included in this group. Mineral salts have a molecular weight of 300 or less.

Positively charged components (cations) include calcium (Ca), potassium (K), sodium (Na), magnesium (Mg) and amines.

Negatively charged components (anions) include phosphate (PO₄), sulfate (SO₄), carbonate (CO₃), chloride (Cl⁻), carboxylic acid and citrate.

Ash – is the residue that remains when milk/whey is heated to very high temperatures in a muffle oven. Organic acids are lost during ashing. Some minerals such as sulfur and phosphorous also may be lost. Other minerals may be converted to oxides, sulfates, phosphates, silicates and chlorides. In general, ash overestimates the concentration of minerals present since oxygen often is combined with minerals in the remaining ash.

Dairy minerals also may be referred to as whey mineral concentrate, milk mineral concentrate or milk calcium.

Regulations
♦ GRAS Notice No. 52 (2001)
### General composition of dairy minerals

<table>
<thead>
<tr>
<th>Component</th>
<th>Dairy minerals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>5</td>
</tr>
<tr>
<td>Lactose</td>
<td>6</td>
</tr>
<tr>
<td>Ash</td>
<td>82</td>
</tr>
<tr>
<td>Fat</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Moisture</td>
<td>6</td>
</tr>
</tbody>
</table>

### General Process for the Manufacture of Dairy Minerals

1. **Whey**
2. **Ultrafiltration/diafiltration**
3. **Permeate (lactose, ash)**
4. **Caustic**
5. **pH adjusted**
6. **Evaporate**
7. **Water**
8. **Retentate (whey proteins, some lactose/ash)**
9. **Precipitated mineral and soluble components**
10. **Separate**
11. **Soluble components (some mineral, lactose)**
12. **Spray dry**
13. **Spray dry**
14. **Reduce mineral whey/Permeate**
15. **Water**
16. **Spray dry**
17. **Dairy Minerals**
Manufacture of Dairy Minerals

Typical composition and characteristics

**Dairy minerals**
- Typical composition
  - Protein (db)*: 4.5%
  - Moisture: 6%
  - Lactose: 6%
  - Fat: < 0.1%
  - Ash: 83%
  - Calcium: 23%
  - Phosphorous (as PO₄): 40%
  - Ca:P: 1.7
- Characteristics
  - Color: white to off white
  - Flavor: clean, salty
  - pH: 6.5
  - Particle size:
    - coarse 95% < 100μm
    - fine 95% < 10μm
- Storage
  - < 25°C, <65% rh
  - 12 to 24 months

* Non protein nitrogen included in this value. May or may not contain true protein.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ADPI</td>
<td>American Dairy Products Institute</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CFSAN</td>
<td>Center for Dood Safety and Applied Nutrition</td>
</tr>
<tr>
<td>CMP</td>
<td>Casein macropeptide</td>
</tr>
<tr>
<td>db</td>
<td>Dry basis</td>
</tr>
<tr>
<td>DBM</td>
<td>Dry buttermilk</td>
</tr>
<tr>
<td>DBP</td>
<td>Dry buttermilk product</td>
</tr>
<tr>
<td>DF</td>
<td>Diafiltration</td>
</tr>
<tr>
<td>DWM</td>
<td>Dry whole milk</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
</tr>
<tr>
<td>FCC</td>
<td>Food Chemical Codex</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GMP</td>
<td>Glycomacropeptide</td>
</tr>
<tr>
<td>GOS</td>
<td>Galacto-oligosaccharides</td>
</tr>
<tr>
<td>GRAS</td>
<td>Generally recognized as safe</td>
</tr>
<tr>
<td>IFNCA</td>
<td>Islamic Food and Nutrition Council of America</td>
</tr>
<tr>
<td>Ig</td>
<td>Immunoglobulin</td>
</tr>
<tr>
<td>IGF</td>
<td>Insulin-like growth factors</td>
</tr>
<tr>
<td>INDM</td>
<td>Instant nonfat dry milk</td>
</tr>
<tr>
<td>MF</td>
<td>Microfiltration</td>
</tr>
<tr>
<td>MPC</td>
<td>Milk protein concentrate</td>
</tr>
<tr>
<td>MPI</td>
<td>Milk protein isolate</td>
</tr>
<tr>
<td>na</td>
<td>Not available</td>
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<tr>
<td>NF</td>
<td>National Formulary</td>
</tr>
<tr>
<td>NDM</td>
<td>Nonfat dry milk</td>
</tr>
<tr>
<td>NFDM</td>
<td>Nonfat dry milk</td>
</tr>
<tr>
<td>NPN</td>
<td>Nonprotein nitrogen</td>
</tr>
<tr>
<td>PMO</td>
<td>Pasteurized Milk Ordinance</td>
</tr>
<tr>
<td>rh</td>
<td>Relative humidity</td>
</tr>
<tr>
<td>SMP</td>
<td>Skim milk powder</td>
</tr>
<tr>
<td>spc</td>
<td>Standard plate count</td>
</tr>
<tr>
<td>TA</td>
<td>Titratable acidity</td>
</tr>
<tr>
<td>UF</td>
<td>Ultrafiltration</td>
</tr>
<tr>
<td>USDA</td>
<td>US Department of Agriculture</td>
</tr>
<tr>
<td>USPHS</td>
<td>United States Public Health Services</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WPC</td>
<td>Whey protein concentrate</td>
</tr>
<tr>
<td>WPI</td>
<td>Whey protein isolate</td>
</tr>
<tr>
<td>WPNI</td>
<td>Whey protein nitrogen index</td>
</tr>
<tr>
<td>WPPC</td>
<td>Whey protein phospholipid concentrate</td>
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</tbody>
</table>

### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>α</td>
<td>Alpha</td>
</tr>
<tr>
<td>β</td>
<td>Beta</td>
</tr>
<tr>
<td>K</td>
<td>Kappa</td>
</tr>
<tr>
<td>μ</td>
<td>Micron</td>
</tr>
<tr>
<td>&gt;</td>
<td>Greater than</td>
</tr>
<tr>
<td>&lt;</td>
<td>Less than</td>
</tr>
<tr>
<td>≥</td>
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<td>≤</td>
<td>Not less than</td>
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<table>
<thead>
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<th>Description</th>
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<td>C</td>
<td>Carbon</td>
</tr>
<tr>
<td>Ca</td>
<td>Calcium</td>
</tr>
<tr>
<td>CaCl</td>
<td>Calcium chloride</td>
</tr>
<tr>
<td>Cl</td>
<td>Chloride</td>
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<tr>
<td>CO₃</td>
<td>Carbonate</td>
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<td>Cu</td>
<td>Copper</td>
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<td>Fe</td>
<td>Iron</td>
</tr>
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<td>H</td>
<td>Hydrogen</td>
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<tr>
<td>HCl</td>
<td>Hydrochloric acid</td>
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<td>Potassium</td>
</tr>
<tr>
<td>Mg</td>
<td>Magnesium</td>
</tr>
<tr>
<td>N</td>
<td>Nitrogen</td>
</tr>
<tr>
<td>NaOH</td>
<td>Sodium hydroxide</td>
</tr>
<tr>
<td>Na</td>
<td>Sodium</td>
</tr>
<tr>
<td>PO₄</td>
<td>Phosphate</td>
</tr>
<tr>
<td>P</td>
<td>Phosphorous</td>
</tr>
<tr>
<td>O</td>
<td>Oxygen</td>
</tr>
<tr>
<td>SO₄</td>
<td>Sulfate</td>
</tr>
<tr>
<td>Zn</td>
<td>Zinc</td>
</tr>
</tbody>
</table>
Websites

American Dairy Products Institute (ADPI)
www.adpi.org

Center for Dairy Research (CDR)
www.cdr.wisc.edu

Code of Federal Regulations (CFR)
www.gpoaccess.gov/cfr

CODEX Alimentarius
www.codexalimentarius.net

Dairy Management, Inc. (DMI)
www.thinkusadairy.org

Food and Drug Administration (FDA)
www.fda.gov

Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
www.cfsan.fda.gov

National Dairy Council (NDC)
www.nationaldairycouncil.org

US Dairy Export Council (USDEC)
www.usdec.org

US Department of Agriculture, Agricultural Marketing Service (USDA, AMS)
www.ams.usda.gov/dairy
Summary Graphs

Composition of dairy ingredients made from milk

Composition of dairy ingredients made from whey