



Infant Formula (IF) Grade Lactose Standard for Dry Blending

Product Definition

Lactose (Milk Sugar) is a white to creamy white crystalline product, possessing a mildly sweet taste. It may be anhydrous; contain one molecule of water of hydration; or may 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 infant consumption complies with all provisions of the U.S. Federal Food, Drug, and Cosmetic Act as well as any foreign regulatory requirements of the nations in which it is consumed.

Composition

| Parameter | Units of Measure | Limits |
|-----------------------------|------------------|--------------|
| Lactose | %, dry basis | 99.0 minimum |
| Protein | %, dry basis | 0.30 maximum |
| Ash (sulphated) | %, dry basis | 0.30 maximum |
| Total moisture ¹ | %, as-is basis | 6.0 maximum |

1 - Includes water of crystallization.

Mesh Size

IF Grade Lactose for Dry Blending can be milled to produce various mesh sizes.

Other Characteristics

| Physico-chemical Properties | | |
|-----------------------------|------------------|---------------|
| Parameter | Units of Measure | Limits |
| Scorched particles | mg/25g | 7.5 maximum |
| pH | 10% solution | 4.5 – 7.5 |
| Aluminum (Al) | mg/kg | 1.00 maximum |
| Tin (Sn) | mg/kg | 10.00 maximum |
| Arsenic (As) | mg/kg | 0.05 maximum |
| Lead (Pb) | mg/kg | 0.02 maximum |
| Mercury (Hg) | mg/kg | 0.03 maximum |
| Manganese (Mn) | mg/kg | 0.20 maximum |
| Copper (Cu) | mg/kg | 2.00 maximum |

| Physico-chemical Properties | | |
|--|------------------|-----------------------------|
| Parameter | Units of Measure | Limits |
| Cadmium (Cd) | mg/kg | 0.02 maximum |
| Nitrites | mg/kg | 2 maximum |
| Nitrates | mg/kg | 50 maximum |
| Aflatoxin M1 | µg/kg | not detected ² |
| Quaternary ammonium compounds (BAC & DDAC) | µg/kg | 10 maximum |
| Radionuclides | Bq/kg | 10 maximum |
| Nonylphenol ethoxylate (NPE) | µg/kg | 50 maximum |
| Color | visual | white to cream white powder |
| Flavor | sensory | slightly sweet |

2 - Where the effective limit of quantitation for the test is 0.1 µg/kg (ppb) then the test result must be not detected in order to comply with this Standard. Where the testing method is capable of quantifying the toxin below 0.1 µg/kg (ppb), then a compliant result must be a value less than 0.1 µg/kg (ppb).

Any microbiological test result, outside of specification throughout a given lot of production, eliminates all product from that lot as IF Grade Lactose for Dry Blending:

| Microbiological Analysis | | |
|--|------------------|---------------------------|
| Parameter | Units of Measure | Limits |
| Standard plate count | CFU/g | 500 maximum |
| Yeast and mold | CFU/g | 10 maximum |
| <i>Escherichia coli</i> | CFU/g | not detected ³ |
| <i>Enterobacteriaceae</i> | CFU/100g | not detected |
| <i>Salmonella</i> | CFU/1500g | not detected |
| <i>Staphylococcus</i> (coagulase positive) | CFU/g | not detected ³ |
| <i>Bacillus cereus</i> | CFU/g | 100 maximum |
| <i>Clostridia</i> (sulfite-reducing) | CFU/g | 100 maximum |
| <i>Cronobacter sakazakii</i> | CFU/300g | not detected |

3 - Where the effective limit of quantitation for the test is 10 CFU/g (such as when a dilution factor of 10 is applied) then the test result must be not detected in order to comply with this Standard. Where the testing method is capable of quantifying microbial counts below 10 CFU/g, then a compliant result must be a value less than 10 CFU/g.

Methods of Analysis

| Parameter | Reference Method |
|------------------------------|------------------------|
| Lactose | ISO 22662 / IDF 198 |
| Protein | AOAC 991.20 (N x 6.38) |
| Moisture | ISO 5537 / IDF 26 |
| Ash | AOAC 942.05 |
| pH | USDA |
| Metals | ICP-AES |
| Standard plate count | AOAC |
| Yeast & mold | AOAC |
| <i>Escherichia coli</i> | AOAC |
| <i>Enterobacteriaceae</i> | ISO 21528 |
| <i>Salmonella</i> | AOAC or FDA BAM |
| <i>Staphylococcus</i> | AOAC |
| <i>Bacillus cereus</i> | FDA BAM |
| <i>Clostridia</i> | ISO 15213 |
| <i>Cronobacter sakazakii</i> | ISO 22964 |

Product Labeling

Recommended identifications: Lactose or Milk Sugar

Typical Applications

Infant Formula Grade Lactose for Dry Blending is specifically suited for use in infant formula manufacturing processes where ingredients are combined “as is” (dry) rather than via rehydration.

Typical Storage & Shipping

Product should be stored, shipped, and utilized according to the manufacturer’s established recommendations. As guidance, product should be stored and shipped in a cool, dry environment with temperature below 80°F and relative humidity below 65%. Stocks should be rotated and utilized in accordance with the manufacturer’s established date of expiration or retest.

Typical Packaging

Multiwall kraft bags with polyolefin inner liner, or other suitable closed containers (e.g., totes) are typical.

Revision History

| Version | Effective Date | Notes |
|---------|----------------|--|
| 1.0* | 2021 | First officially approved version of this new ingredient standard. |
| 2.0* | 2022 | Revised to increase the minimum pH limit from 4.0 to 4.5; and to incorporate a table of reference methods of analysis for the basic compositional parameters. |
| 3.0 | 06/16/2023 | Migrated this Standard to the new modernized format as authorized by the ADPI Standards Committee. No previously established test parameters or limits were materially altered by this update, but this revision did require footnotes to clarify the inclusion of water of crystallization in total moisture; and the restated acceptance criteria for aflatoxin M1, <i>E. coli</i> , and <i>Staphylococcus</i> . |
| 3.1 | 08/18/2023 | Corrected a typographical error in the sample size for <i>Salmonella</i> which occurred in the 06/16/2023 transcription from the old format to the new. Erroneous sample size was 500 g, correct sample size is 1500 g in alignment with 21 CFR §106.55. |

* - assigned *ex post facto*