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
Escherichia coli	CFU/g	not detected[3]
Enterobacteriaceae	CFU/100g	not detected
Salmonella	CFU/1500g	not detected
Staphylococcus (coagulase positive)	CFU/g	not detected[3]
Bacillus cereus	CFU/g	100 maximum
Clostridia (sulfite-reducing)	CFU/g	100 maximum
Cronobacter sakazakii	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
Escherichia coli	AOAC
Enterobacteriaceae	ISO 21528
Salmonella	AOAC or FDA BAM
Staphylococcus	AOAC
Bacillus cereus	FDA BAM
Clostridia	ISO 15213
Cronobacter sakazakii	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, *E. coli*, and *Staphylococcus*.
3.1	08/18/2023	Corrected a typographical error in the sample size for *Salmonella* 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*