



TECHNICAL INFORMATION

Kerry Inc.
3330 Millington Road Beloit, WI 53511 USA
Tel: 608.299.5100
www.kerry.com

PRODUCT SPECIFICATION

PRODUCT DETAILS

Part Number	Multiple
SAP Code	Multiple
Product Name	SHEFFIELD LACTOSE ANHYDROUS NF IMPALPABLE
Product Description	Lactose is a disaccharide obtained from the whey fraction of milk consisting of one glucose and one galactose moiety. Anhydrous Lactose NF Impalpable, Sheffield brand of Kerry Bio-Science, meets all requirements of the current National Formulary, the European Pharmacopeia, and the Japanese Pharmacopeia. All ingredients are certified rennet free.

INGREDIENT DECLARATION

Anhydrous Lactose
(Contains Milk)

USAGE DETAILS

Anhydrous Lactose NF Impalpable is recommended as an excipient, filler, diluent, and bulking agent in a wide variety of pharmaceutical tablets, capsules, powders and other preparations. It also has applications as a nutrient and multifunctional ingredient in infant formulas, geriatric, dietetic and health foods and may be used as an ingredient in culture media.



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KEY PERFORMANCE PARAMETERS

	Min	Max	Units	Method
Water Content		1	%	Karl Fischer
Acidity		0.4	%	mL 0.1N NaOH, 6 g/ 25 mL
Residue on Ignition		0.1	%	
Loss on drying		0.5		80 °C
Protein & LAI @ 210-220 nm		0.25		Absorbance
Protein & LAI @ 270-300 nm		0.07		Absorbance
Clarity		0.04		And Color, Absorbance @ 400 nm
Specific Rotation	54.4	55.9		+ degrees, Polirimeter

All lactose passes identification tests A & B.

Alpha and beta anomers have been analyzed for this product. However, there are no specifications.

Lactose Anhydrous NF Impalpable is free-flowing, non-hygroscopic powder, white in color. A 10% solution (in boiling water) is clear and nearly colorless. Solubility in water @ 25 °C (77 °F) is 20 g/100 mL.

PARTICLE SIZE DISTRIBUTION

Particle size Laser, % > 100 mesh (150 µm) screen	0 - 5
Particle size Laser, % > 140 mesh (106 µm) screen	0 - 10
Particle size Laser, % > 200 mesh (75 µm) screen	0 - 15
Particle size Laser, % > 325 mesh screen (45 µm) screen	10 - 40
Particle size Laser, % > 500 mesh screen (25 µm) screen	35 - 60

PHYSICAL DESCRIPTION

Color: White
Form: Powder
Aroma: Odorless

ADDITIONAL INFORMATION

MANUFACTURING LOCATION:

10202 Foremost Drive, Rothschild, WI 54474 USA



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MICROBIOLOGICAL DATA

E. Coli	NOT DETECTED	NF/10 g
Salmonella	NOT DETECTED	JP/60 g
Aerobic Plate Count	< 100 cfu/g	CFU/g, NF/10 g
Yeasts & Moulds	< 50 cfu/g	CFU/g, NF/10 g

SHELF-LIFE & STORAGE

1095 days unopened Storage conditions are: Keep container tightly closed. Avoid excessive heat, protect from moisture, do not freeze.

PACKAGING

Packaging Type: Drum/Can
80 KG, 100 LB, or 200 LB drum, 25 KG bag; polyethylene liner



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NUTRITIONAL INFORMATION

Nutrient	Typical Value	Unit	Method / Source
Calories	396.0	kcal/100g	Calculated
Calculated Energy in KJ (for Kerry only)	0.0	kJ/100g	Calculated
Calories from Fat	0.0	kcal/100g	Calculated
Total Fat	0.0	g/100g	Calculated
Saturated Fat	0.0	g/100g	Calculated
Trans Fat	0.0	g/100g	Calculated
Cholesterol	0.0	mg/100g	Calculated
Total Carbohydrate	99.0	g/100g	Calculated
Sugars	99.0	g/100g	Calculated
Dietary Fiber	0.0	g/100g	Calculated
Protein	0.0	g/100g	Calculated
Iron	0.0	mg/100g	Calculated
Sodium	0.0	mg/100g	Calculated
Vitamin A	0.0	IU/100G	Calculated
Vitamin C	0.0	mg/100g	Calculated
Calcium	3.0	mg/100g	Calculated

Note: The information stated is given in good faith and is based upon the product formulation and data provided by raw material suppliers. While we make every effort to obtain assurances from our suppliers regarding the nutritional data supplied, manufacturers and/or suppliers do not always test their materials to obtain nutritional data and therefore will not always provide absolute values.

RECOMMENDED ALLERGEN DATA FOR LABELING PURPOSES

Is the product FREE FROM...?	Yes = Absent, No = Present
Dairy/Dairy Derivatives	NO
Egg/Egg Derivatives	YES
Soy/Soy Derivatives	YES
Wheat/Wheat Derivatives	YES
Peanuts/Peanut Derivatives	YES
Treenut/Treenut Derivatives	YES
Fish/Fish Derivatives	YES
Shellfish/Shellfish Derivatives	YES



Code:
Issue date:

Multiple
1/10/2018

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LEGISLATION & WARRANTY STATEMENT

The product will be manufactured in accordance with all current relevant US legislation. The information stated is given in good faith and is based upon the product formulation and the data provided by our raw material suppliers.
All reasonable precautions that could be expected of a responsible manufacturer have been taken, however no absolute guarantees can be given that trace / carry over residues will be totally absent.

CONFIDENTIALITY

This specification and the information contained within it remains the property of this company and must not be disclosed to any third party without the prior written permission of the company.