



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 MONOHYDRATE NF CAPSULATING GRADE
Product Description	Lactose is a disaccharide obtained from the whey fraction of milk consisting of one glucose and one galactose moiety. Lactose Monohydrate NF Capsulating Grade, Sheffield™ brand of Kerry Bio-Science, is the crystalline alphanohydrate. Lactose Monohydrate NF Capsulating Grade meets all requirements of the current National Formulary, the European Pharmacopeia, and the Japanese Pharmacopeia. All ingredients are certified rennet free.

INGREDIENT DECLARATION

Lactose Monohydrate

Contains Milk

Kosher, Dairy

USAGE DETAILS

Lactose Monohydrate NF Capsulating Grade 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 multi-functional 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	4.5	5.5	%	Karl Fischer
Acidity		0.4	%	mL 0.1N NaOH, 6 g/ 25 mL
Residue on Ignition		0.1	%	Sulfated Ash
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, Polarimeter

All lactose passes Identification Tests A & B

Lactose Monohydrate NF Capsulating Grade 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 Ro-tap,	% on 80 mesh (180 µm) screen	0 - 2
Particle size Ro-tap,	% on 100 mesh (150 µm) screen	0 - 6
Particle size Ro-tap,	% on 200 mesh (75 µm) screen	27 - 39
Particle size Ro-tap,	% thru 200 mesh screen	58 - 70

PHYSICAL DESCRIPTION

Color: White
Form: Powder
Aroma: Odorless

ADDITIONAL INFORMATION

MANUFACTURING LOCATIONS:

10202 Foremost Drive, Rothschild, WI 54474 USA



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MICROBIOLOGICAL DATA

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

SHELF-LIFE & STORAGE

1460 days unopened Keep container tightly closed. Avoid excessive heat, protect from moisture, do not freeze

PACKAGING

Packaging Type: Polyethylene Lined Fibre Drum
80 KG drum, 100 LB drum, 200 LB drum, 25 KG bag with polyethylene liner.



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NUTRITIONAL INFORMATION

Nutrient	Typical Value	Unit	Method / Source
Calories	380.0	kcal/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	95.0	g/100g	Calculated
Sugars	95.0	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	2.0	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
Gluten/Gluten 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.