



Code:
Issue date:

Multiple
1/10/2018

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	LUBRITOSE SD
Product Description	LubriTose™ SD is a co-processed excipient consisting of NF/Ph. Eur./JP compliant Spray Dried Lactose and NF/ JP compliant Glyceryl Monostearate. The co-processed formula is 96% Spray Dried Lactose as the compressible ingredient and 4% Glyceryl Monostearate as a lubricant. The co-processing process results in a uniform physical dispersion of the Glyceryl Monostearate and the chemical attributes of both ingredients remain in tact. A drug master file (DMF) is in place for the product.

INGREDIENT DECLARATION

Ingredient	CAS number
Spray Dried Lactose (NF,Ph. Eur.,JP)	64044-51-5
Glyceryl Monostearate (NF, JP)	123-94-4

Contains Milk



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USAGE DETAILS

LubriTose™ SD is meant to be used in standard direct tableting applications. It is only necessary to add the API (active pharmaceutical ingredient), any other desired ingredient, and proceed to tableting. The Glyceryl Monostearate is co-processed in to act as a lubricant and therefore it is not necessary to add a lubricant such as Magnesium Stearate to the tableting formulation. By using LubriTose™, you get a true direct tableting operation as the lubricant addition step is removed. LubriTose™ is ideal for continuous systems and also for QbD.

KEY PERFORMANCE PARAMETERS

	Min	Max	Units	Method
Water Content			%	Record, Karl Fisher
Residue on Ignition			%	Record, Sulfated Ash
Loss on drying		2		80 °C, %, 2 hours
Identity	IR Scan	Matches Standard		
Lactose	IR Scan - %	94.0 – 98.0		

PARTICLE SIZE DISTRIBUTION

Particle Size, % Rotap, >40 mesh (425 µm) 0-8%
Particle Size, % Rotap, >100 mesh (180 µm) 0-25%
Particle Size, % Rotap, >200 mesh (75 µm) 50-85%

PHYSICAL DESCRIPTION

Color: White
Form: Powder

MICROBIOLOGICAL DATA

Yeast < 100 cfu/g And Mold, USP/10g, CFU/g

SHELF-LIFE & STORAGE

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



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PACKAGING

Packaging Type: Drum/Can
200 LB

NUTRITIONAL INFORMATION

Nutrient	Typical Value	Unit	Method / Source
Calories	218.4	kcal/100g	Calculated
Calories from Fat	36.0	kcal/100g	Calculated
Total Fat	4.0	g/100g	Calculated
Saturated Fat	4.0	g/100g	Calculated
Trans Fat	0.0	g/100g	Calculated
Cholesterol	0.0	mg/100g	Calculated
Total Carbohydrate	45.6	g/100g	Calculated
Sugars	45.6	g/100g	Calculated
Dietary Fiber	0.0	g/100g	Calculated
Protein	0.0	g/100g	Calculated
Iron	0.0	mg/100g	Calculated
Sodium	0.5	mg/100g	Calculated
Vitamin A	0.0	IU/100G	Calculated
Vitamin C	0.0	mg/100g	Calculated
Calcium	4.8	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



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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

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.