



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 MCC
Product Description	LubriTose™ MCC is a co-processed excipient consisting of NF/Ph. Eur./JP compliant Microcrystalline Cellulose and NF/JP compliant Glyceryl Monostearate where in the chemical attributes of both products are preserved. LubriTose™ MCC was specifically designed to eliminate processing issues , product rejections and tablet press speed limitations typically encountered when Magnesium Stearate is used as the lubricant.

INGREDIENT DECLARATION

Ingredient	CAS number
Microcrystalline Cellulose (NF, Ph. Eur.,JP), E460	9004-34-6
Glyceryl Monostearate (NF, JP), E471	123-94-4

USAGE DETAILS

LubriTose™ MCC 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 .



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KEY PERFORMANCE PARAMETERS

	Min	Max	Units	Method
Loss on drying		5		80 C, %, 2 hours
Uniformity	Cellulose as Insolubles, %			Formula Specific
Water	Karl Fisher			Record
Residue on Ignition	Sulfated Ash			Record

PARTICLE SIZE DISTRIBUTION

Particle Size, % Rotap, >40 mesh (425 µm)	0-10%
Particle Size, % Rotap, >100 mesh (180 µm)	45-80%
Particle Size, % Rotap, >200 mesh (75 µm)	10-60%

PHYSICAL DESCRIPTION

Color: White
Form: Powder
Aroma: Odorless

MICROBIOLOGICAL DATA

Aerobic Plate Count	< 100 cfu/g	USP/10 g
Yeasts & Moulds	< 50 cfu/g	USP/10 g

SHELF-LIFE & STORAGE

730 days unopened Avoid excessive heat. Protect from moisture. Do not freeze.

PACKAGING

Packaging Type: Polyethylene Lined Fibre Drum
20 kg bag, 200 lb drum



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NUTRITIONAL INFORMATION

Nutrient	Typical Value	Unit	Method / Source
Calories	402.7	kcal/100g	Calculated
Calories from Fat	18.5	kcal/100g	Calculated
Total Fat	2.1	g/100g	Calculated
Saturated Fat	2.0	g/100g	Calculated
Trans Fat	0.0	g/100g	Calculated
Cholesterol	0.0	mg/100g	Calculated
Total Carbohydrate	96.0	g/100g	Calculated
Sugars	0.0	g/100g	Calculated
Dietary Fiber	96.0	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	0.0	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	YES
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.