



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	DISINTEQUIK MCC 25
Product Description	Sheffield™ Tableting System Disintequik MCC 25 is a co-processed excipient consisting of 75% Alpha monohydrate lactose and 25% Microcrystalline Cellulose (MCC). The processing results in a co-agglomeration compound of the two ingredients, spray dried lactose and MCC, preserving the identity of each component. Prior to processing, both ingredients meet all of the requirements as outlined in the current monographs of the EU, JP, and NF. Disintequik MCC 25 reduces raw material QC testing, manufacturing steps and process validation. A Drug Master File is available.

INGREDIENT DECLARATION

Lactose, Monohydrate, NF
Microcrystalline Cellulose, NF



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USAGE DETAILS

Sheffield™ Tableting System Disintequik MCC 25 is a co-processed Lactose/MCC excipient designed for direct tableting operations where hard tablets and fast disintegration is required. The unique process synergistically combines the properties of the lactose and MCC and also eliminates blending issues, resulting in a uniform formulation. The combined properties of superior binding capabilities of lactose and the disintegration of MCC allow for small quantities of active and permits tablets to be made without granulating. Disintequik MCC 25 is more fluid more compressible and produces tablets with higher breaking strength than a straight lactose MCC blend. Added benefits include: reduction of blending issues, low dust generation, the avoidance of costly wet granulation processes, improved flowability and content uniformity during compression.

KEY PERFORMANCE PARAMETERS

	Min	Max	Units	Method
Water Content		7	%	Karl Fisher, %
Residue on Ignition		.2	%	Sulfated Ash, %
Loss on drying		3.5		80 °C, %
Identity	Matches Standard			IR Scan
ID of Lactose	Meets			USP Method C
Lactose	73 - 77			Lactose Titration, %
Cellulose	23 - 27			Cellulose as Insolubles, %
pH	4.0-7.0			pH

PARTICLE SIZE DISTRIBUTION

Particle Size Rotap, %	>60mesh	2.0 Max
Particle Size Rotap, %	>140 mesh	25 - 65
Particle Size Rotap, %	>200 mesh	50.0 Min

PHYSICAL DESCRIPTION

Color: White
Form: Powder
Aroma: Odorless



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MICROBIOLOGICAL DATA

E. Coli	NOT DETECTED	NF/10g
Pseudomonas Aeruginosa	NOT DETECTED	NF/10g
Staphylococcus aureus	NOT DETECTED	NF/10g
Salmonella	NOT DETECTED	NF/100g
Aerobic Plate Count	< 100 cfu/g	USP/10g, CFU/g
Yeasts & Moulds	< 50 cfu/g	USP/10g, CFU/g

SHELF-LIFE & STORAGE

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

PACKAGING

Packaging Type: Polyethylene Lined Fibre Drum
25 kg bag, 75 kg drum



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NUTRITIONAL INFORMATION

Nutrient	Typical Value	Unit	Method / Source
Calories	300.0	kcal/100g	Calculated
Calories from Fat	0.0	kcal/100g	Calculated
Total Fat	0.2	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	75.0	g/100g	Calculated
Sugars	75.0	g/100g	Calculated
Dietary Fiber	24.0	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	6.9	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.