



## 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 ODT
Product Description	Sheffield™ Disintequik ODT is a co-processed excipient consisting of mannitol, monohydrate lactose, dextrose monohydrate, and crospovidone. The processing results in a co-agglomeration compound of the four ingredients preserving the identity of each component. Prior to processing, all ingredients meet all of the requirements as outlined in the current monographs of USP/NF. Sheffield™ Disintequik ODT reduces raw material QC testing, manufacturing steps and process validation.

### INGREDIENT DECLARATION

Ingredient	E#	CAS number
Lactose Monohydrate (USP, Ph. Eur., JP)		64044-51-5
Mannitol (USP, Ph. Eur.)	E421	69-65-8
Dextrose Monohydrate (USP)	E418	5996-10-1
Crospovidone (USP, Ph. Eur., JPE)	E1201	9080-59-5



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## USAGE DETAILS

Sheffield™ Disintequik ODT is a co-processed excipient designed for direct tableting operations for use in orally disintegrating tablets in that the tablet is designed to be dissolved on the tongue rather than swallowed whole. An additional convenience is that the tablet can be taken without water. It can be blended with a flavor, active, suitable lubricant, additional sweetener if desired, and then directly compressed into tablets. The combined properties of superior binding capabilities of lactose, the rapid dissolution time of croscopolidone and the smooth mouth feel of the mannitol, allow for the final dosage to be meet the definition of an orally disintegrating tablet as outlined in the USP method <701> in that the ODT tablet should disintegrate in less than 30 seconds. Sheffield™ Disintequik ODT is more fluid, more compressible, and produces tablets with higher breaking strength than other available ODT formulations on the market. Added benefits include: directly packing into bottles instead of the need for blister packs, reduction of blending issues, low dust generation, pre-formulated to eliminate the need for licensing, the avoidance of costly freeze drying processes, improved flowability, and content uniformity during compression.

## KEY PERFORMANCE PARAMETERS

	Min	Max	Units	Method
Residue on Ignition		5	%	Sulfated Ash, %
Loss on drying		6		80 °C, %, 2 hours

## PARTICLE SIZE DISTRIBUTION

Particle Size	% Rotap, >40 mesh (425 µm)	0-5%
Particle Size	% Rotap, >80 mesh (180 µm)	0-10%
Particle Size	% Rotap, >200 mesh (45 µm)	20-45%

## PHYSICAL DESCRIPTION

**Color:** White  
**Form:** Powder  
**Aroma:** Odorless

## SHELF-LIFE & STORAGE

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



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## PACKAGING

**Packaging Type:** Polyethylene Lined Fibre Drum  
25 kg bag, 100 lb drum, 200 lb drum

## NUTRITIONAL INFORMATION

Nutrient	Typical Value	Unit	Method / Source
Calories	250.4	kcal/100g	Calculated
Calories from Fat	1.4	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	62.3	g/100g	Calculated
Sugars	62.3	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	2.5	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



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<b>Is the product FREE FROM...?</b>	<b>Yes = Absent, No = Present</b>
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.