



## 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	Aero Flo 65 Monohydrate
Product Description	Lactose is a disaccharide obtained from the whey fraction of milk consisting of one glucose and one galactose moiety. Aero Flo 65 Monohydrate meets all requirements of the current National Formulary, the European Pharmacopeia, and the Japanese Pharmacopeia. All ingredients are certified rennet free.

### INGREDIENT DECLARATION

Lactose Monohdrate

Kosher, Dairy

(Contains Milk)

### USAGE DETAILS

Aero Flo 65 Monohydrate is recommended as an excipient, filler, and carrier for dry powder inhalation applications.



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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
Specific Rotation	54.4	55.9		+ degrees, Polarimeter
Residue on Ignition		.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		.04		and Color, Absorbance @ 400 nm
Endotoxins		5	Eu/g	LAL, Gel-Clot

All Lactose passes Identification Tests A & B

Aero Flo 65 Monohydrate is a free-flowing, non-hygroscopic powder, white in color. A 10% solution (in boilingwater) is clear and nearly colorless. Solubility in water @ 25 °C (77 °F) is 20 g/100 mL.

### PARTICLE SIZE DISTRIBUTION

Particle Size Laser, D (v, 0.1)	9-18
Particle Size Laser, D (v, 0.5)	55-70
Particle Size Laser, D (v, 0.9)	135-160

### PHYSICAL DESCRIPTION

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



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### ADDITIONAL INFORMATION

#### MANUFACTURING LOCATIONS:

10202 Foremost Drive, Rothschild, WI 54474 USA

### MICROBIOLOGICAL DATA

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

### SHELF-LIFE & STORAGE

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

### PACKAGING

**Packaging Type:** Drum/Can  
25 KG polyethylene drum 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.