



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 25 Anhydrous |
| Product Description | Lactose is a disaccharide obtained from the whey fraction of milk consisting of one glucose and one galactose moiety. Aero Flo 25 Anhydrous meets all requirements of the current National Formulary, the European Pharmacopeia, and the Japanese Pharmacopeia. All ingredients are certified rennet free. |

INGREDIENT DECLARATION

Anhydrous Lactose
(Contains Milk)

USAGE DETAILS

Aero Flo 25 Anhydrous is recommended as an excipient, filler, and for dry powder inhalation applications.



TECHNICAL INFORMATION

Kerry Inc.
3330 Millington Road Beloit, WI 53511 USA
Tel: 608.299.5100
www.kerry.com

KEY PERFORMANCE PARAMETERS

| | Min | Max | Units | Method |
|----------------------------|------|------|-------|--------------------------------|
| Water Content | | 1 | % | Karl Fisher |
| Acidity | | 0.4 | % | mL 0.1N NaOH, 6 g/ 25 mL |
| Specific Rotation | 54.4 | 55.9 | | + degrees, Polarimeter |
| Residue on Ignition | | 0.1 | % | Sulfated ash, % |
| Loss on drying | | 0.5 | | %, 80 °C |
| Protein & LAI @ 210-220 nm | | 0.25 | | Absorbance @ 210 - 220 nm |
| Protein & LAI @ 270-300 nm | | 0.07 | | Absorbance @ 270 - 300 nm |
| Clarity | | 0.04 | | And color, Absorbance @ 400 nm |
| Endotoxins | | 5 | Eu/g | LAL, Gel Clot |

All lactose passes identification tests A & B.
Alpha and beta anomers have been analyzed for this product. However, there are no specifications. Aero Flo 25 Anhydrous is free-flowing, non-hygroscopic powder, white in color. A 10% solution (in boiling water) 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) | 1-6 |
| Particle Size Laser, D (v, 0.5) | 18-30 |
| Particle Size Laser, D (v, 0.9) | 60-85 |

PHYSICAL DESCRIPTION

Color: White
Form: Powder
Aroma: Odorless

ADDITIONAL INFORMATION

MANUFACTURING LOCATION:

10202 Foremost Drive, Rothschild, WI 54474 USA



TECHNICAL INFORMATION

Kerry Inc.
3330 Millington Road Beloit, WI 53511 USA
Tel: 608.299.5100
www.kerry.com

MICROBIOLOGICAL DATA

| | | |
|---------------------|--------------|-----------------------|
| E. Coli | NOT DETECTED | NF/10g |
| Enterobacteriaceae | < 10 cfu/g | CFU/ g, ISO/10 g |
| Salmonella | NOT DETECTED | Japanese/Pharmacopeia |
| Aerobic Plate Count | < 100 cfu/g | CFU/g, NF/10g |
| Yeasts & Moulds | < 50 cfu/g | 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.



TECHNICAL INFORMATION

Kerry Inc.
3330 Millington Road Beloit, WI 53511 USA
Tel: 608.299.5100
www.kerry.com

NUTRITIONAL INFORMATION

| Nutrient | Typical Value | Unit | Method / Source |
|--|---------------|-----------|-----------------|
| Calories | 396.0 | kcal/100g | Calculated |
| Calculated Energy in KJ (for Kerry only) | 0.0 | kJ/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 | 99.0 | g/100g | Calculated |
| Sugars | 99.0 | 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 | 3.0 | 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 |



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

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.