Version	00
Molecular weight	360.30
Quality Test / Release Date	02/17/2020
Molecular Formula	C12 H22 O11 . H2 O
CAS No	5989-81-1
Linear Formula	
Flash Point (°C)	

Certificate of Analysis

This is to certify that units of the lot number below were tested and found to comply with the specifications of the grade listed. Certain data have been supplied by third parties. Acros Organics expressly disclaims all warranties,expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. Products are for research use or further manufacturing. Not for direct administration to human or animals. It is the responsiblity of the purchaser, formulator or those performing further manufacturing to determine suitability based upon the intended use of the end product. Products are tested to meet the analytical requirements of the noted grade. The following information is the actual analytical results obtained.

Catalog Number	36889	**Quality Test / Release Date** 02/17/2020
Lot Number	A0416732	
Description	alpha-D-Lactose monohydrate,USP/NF, Ph.Eur., JP	
Country of Origin	NETHERLANDS	
Declaration of Origin	bovine (cattle)	

BSE/TSE comment	

Chemical Comment	

Result name	Units	Specifications	Test Value
Appearance (Color)		White to almost white	White
Appearance (Form)		Amorphous powder, crystals or crystalline powder	Amorphous powder
Identification		Conform USP/NF, EP, JP	Conform USP/NF, EP, JP
Appearance of solution		Clear and not more intensely colored than ref. BY7	Clear and not more intensely colored than ref. BY7
Clarity and color of solution		Clear and nearly colorless	Clear colorless
Residue after ignition		=<0.1 %	0.02 %
Water		4.5 to 5.5 %	5.3 %
Loss on drying		=<0.5 % (80°C, 2 h)	0.09 % (80°C, 2 h)
Acidity/alkalinity		=<0.4 ml/6g (ml 0.1N NaOH/6g)	=<0.2 ml/6g (ml 0.1N NaOH/6g)
Specific optical rotation		+54.4° to +55.9° (20°C, 589 nm) (c=10, H2O/NH3)	+54.5° (20°C, 589 nm) (c=10, H2O/NH3)
Specific optical rotation		After 30 min., on anhydrous substance	After 30 min., on anhydrous substance
UV		(1 % in water) 1 cm cell	(1 % in water) 1 cm cell
UV		at 210 nm A: =<0.25	at 210 nm A:0.05
UV		at 220 nm A: =<0.25	at 220 nm A:0.032
UV		at 270 nm A: =<0.07	at 270 nm A:0.02
UV		at 300 nm A: =<0.07	at 300 nm A:0.01

Result name	Units	Specifications	Test Value
UV		(c=10, 1 cm cell)	(c=10, 1 cm cell)
UV		at 400 nm A: =<0.04	at 400 nm A:0.004
Heavy metals		=<5 ppm	=<5 ppm
Microbial contamination		=<100 CFU/g total aerobic microbial count	=<100 CFU/g total aerobic microbial count
Microbial contamination		=<50 CFU/g total yeasts and moulds	=<10 CFU/g total yeasts and moulds
Microbial contamination		(Escherichia coli in 10 g) Absent	(Escherichia coli in 10 g) Absent
Microbial contamination		(Salmonellae in 100 g) Absent	(Salmonellae in 100 g) Absent
Particle size		50 to 65 % (=< 45 µm)	58 % (=< 45 µm)
Particle size		>=90 % (=< 100 µm)	94 % (=< 100 µm)
Particle size		>=96 % (=< 150 µm)	100 % (=< 150 µm)
Particle size		>=99 % (=< 250 µm)	100 % (=< 250 µm)

L. Van den Broek, QA Manager Issued: 02-18-2020

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