



Specification

Concerning Product:	
Article number	10039266BPEUL
Trade name / designation / denomination	Lactose-Monohydrat, EP/USP
CAS number	10039-26-6
Other names / synonyms	•D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1);
EC number	600-087-0
Molecular weight [g / mol]	342,29
Formula	C ₁₂ H ₂₂ O ₁₁

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	Ph. Eur. 2.2.1	≤ 3	
Appearance of solution	Ph. Eur. 2.2.2	The solution should not be more colored than the color comparison solution BG7	
Physical parameter			
Acidity/Alkalinity		≤ 0,4	ml
Loss on drying		≤ 0,5	%
Loss on drying		4,5 – 5,5	%
Specific Optical Rotation		54,4 – 55,9	°
Identity			
Identification		B:complies	
Identification		D:complies	
Identification		A:complies	
Infrared absorbtion spectrometry	Ph. Eur. 2.2.25	Absorption: proteins and light-absorbing impurities at 210 to 220 nm ≤ 0,25	
Infrared absorbtion spectrometry	Ph. Eur. 2.2.25	Absorption: proteins and light-absorbing impurities at 270 to 300 nm ≤ 0,07	
Infrared absorbtion spectrometry	Ph. Eur. 2.2.25	Absorption: proteins and light-absorbing impurities at 400 nm ≤ 0,04	
Impurities			
Heavy Metals (as Pb)		≤ 5	µg/g
Sulphated ash		≤ 0,1	%
Microbiological data			
Aerobic microorganisms		≤ 100	KBE/g
Escherichia Coli.		neg. in 10g	CFU/g
Salmonella		neg. in 10g	
Yeast and Mould		≤ 50	KBE/g
Particle size distribution			
Particles		< 100 µm: ≥ 90	%
Particles		< 32 µm: 45 – 75	%

Supplemental information:

Storage conditions: Well sealed container. Store in an unopened original container at room temperature in a dry and odorless environment.

Regional origin: D

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 13. Dec. 2019

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