

Lactose monohydrate

CODE ARTICLE: 92662	BATCH: 0134490
TEST DATE: 16/09/2024	TEST: QC-00267995
EXPIRY DATE: 17/02/2027	FABRICATION DATE: 18/02/2024
CAS: [10039-26-6]	MR: 360,31
FORMULA: C ₁₂ H ₂₂ O ₁₁ ·H ₂ O	
SYNONYMS / BOTANICAL NAME: Azúcar de leche; Lactobiosa; Saccharum lactis; lactina; Lactol	
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION [A]	PASS				PH.EUR.*
IDENTIFICACION AGUA [D]	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			Clear and B and 7	PH.EUR.
ACIDITY/ALCALINITY	0,15 ml NaOH/6g		0,0	0,4	PH.EUR.
ROTAC.ESPECIFICA (BASE ANHIDRA)	55 DEGREES		54,4	55,9	PH.EUR.
ABSORBANCIA					
ABSORBANCE 215nm	0,027 -		0,0	0,25	PH.EUR.
ABSORBANCIA 276nm	0,013 -		0,0	0,07	PH.EUR.
ABSORBANCE 400nm	0,004 -		0,0	0,04	PH.EUR.
WATER	5 %		4,5	5,5	PH.EUR.*
SULPHATED ASHES	0,1 %		0,0	0,1	PH.EUR.
MICROBIOLOGICAL CONTROL					
TOTAL AEROBICS	<100 UFC/G			100	PH.EUR.
E. COLI	ABSENT/g				PH.EUR.
PH	5,5 -		-	-	Manufacture's Standard*
ASSAY	99,87 %				Manufacture's Standard
SCORCHED PARTICLES	A -			A-B	Manufacture's Standard
HEAVY METALS	<5 ppm			5	Manufacture's Standard
PARTICLE SIZE					
TAMAÑO PARTICULA >45 MICRAS	47 %		-	-	Manufacture's Standard
TAMAÑO PARTICULA >75 MICRAS	28,1 %		-	-	Manufacture's Standard
PARTICLE SIZE 100 MICRON	17,2 %		-	-	Manufacture's Standard
PARTICLE SIZE >150 MICRONS	6 %		-	-	Manufacture's Standard
PARTICLE SIZE 250 MICRON	0,2 %		-	-	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
RESIDUAL SOLVENTS	COMPLIES ICH Q3C				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer Batch: 0000106190 Manufacturer Code: 56850 Supplier Code: 405999

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



Lactose monohydrate

CODE ARTICLE: 92662	BATCH: 0134490
TEST DATE: 16/09/2024	TEST: QC-00267995
EXPIRY DATE: 17/02/2027	FABRICATION DATE: 18/02/2024
CAS: [10039-26-6]	MR: 360,31
FORMULA: C ₁₂ H ₂₂ O ₁₁ ·H ₂ O	
SYNONYMS / BOTANICAL NAME: Azúcar de leche; Lactobiosa; Saccharum lactis; lactina; Lactol	
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
Risk Assessment Evaluation for Nitrosamines	PASS				Manufacture's Standard



Silvia Sancho-Tello Ripoll
Technical Director.

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer Batch: 0000106190 Manufacturer Code: 56850 Supplier Code: 405999

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
 Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com

