

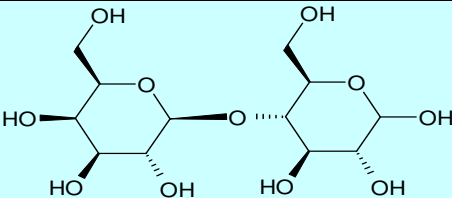


SDFCL
s d fine-chem limited

Quality Control Dept.



Product Specification

E Control	QC2\DATAD\DA\PS\20139XPS.xls		
PRODUCT CODE	20139		
PRODUCT NAME	LACTOSE MONOHYDRATE AR Meets Analytical Specification of IP, BP, Ph. Eur. (for Bacteriology)		
SYNONYMS	(α-Lactose monohydrate)		
C.I. NO.	--		
CASR NO.	(10039-26-6)		
ATOMIC OR MOLECULAR FORMULA	C ₁₂ H ₂₂ O ₁₁ .H ₂ O		
ATOMIC OR MOLECULAR WEIGHT	360.31		
PROPERTIES	Sweet taste, odourless , stable in air ,insoluble in chloroform and ether.		
			
PARAMETER	LIMIT		
Description	A white to almost white crystalline powder.		
Solubility	10% solution in hot water (50°C) is clear.		
Identification (By FTIR)	Conforms.		
Specific Rotation (α) _D (C=10%, in water & 0.2 ml dil. NH ₃)	+54.4° to +55.9°		
Absorbance/Light absorption	Passes test.		
Water (By KF)	4.5 - 5.5%		
Sulphated ash	Max. 0.05%		
MAXIMUM LIMIT OF IMPURITIES			
Insoluble matter	0.005%		
Acidity or alkalinity	Passes test.		
Free Acid	0.5 ml N/1%		
Alcohol soluble impurities	0.2%		
Arsenic (As)	0.0001%		
Copper (Cu)	0.00005%		
Iron (Fe)	0.0002%		
Heavy metals (as Pb)	0.0001%		
Microbial contamination	NMT 100 org/g		
Note(s) : Assay (if applicable) method mentioned.			
WARNING Hazard statements : Not hazardous. No hazards. Precautionary statements Prevention: ----- Response: ---			IMDG Code : -- UN No. : -- IATA : --
Disposal: -----			
Hazard Pictogram(s) :--			
Prepared By : Name/Dept. : Officer (Q.A.) Sign. : Date : 01.04.2010	Checked By: Name/Dept.:Incharge(Q.A.) Sign. : Date : 01.04.2010	Approved By: Name/Dept. : Incharge (Tech.) Sign. : Date : 02.04.2010	Issue Date : 01.07.2002 Revision No.: 04 Revision dt. : 02.04.2010 AMEND NO. : 1554

