

# LACTOSE MONOHYDRATE EXTRA PURE

## Safety Data Sheet

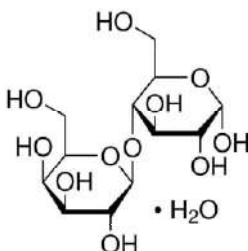
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Substance  
Trade name : LACTOSE MONOHYDRATE EXTRA PURE  
EC-No. : 600-087-0  
CAS-No. : 10039-26-6  
Product code : B-01498  
Type of product : Carbohydrate  
Formula : C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · H<sub>2</sub>O  
Chemical structure :



Synonyms : Milk sugar, D-Lactose Monohydrate,  $\beta$ -D-Gal-(1 $\rightarrow$ 4)-D-Glc, 4-O- $\beta$ -D-Galactopyranosyl-D-glucose Monohydrate,

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### Relevant identified uses

Use of the substance/mixture : Laboratory chemicals, Manufacture of substances

#### 1.3. Details of the supplier of the safety data sheet

Bio-Chem Chemicals  
5455, Nicholson Road Science Market,  
Ambala Cantt. 133001 Haryana (India)  
+91-82952 41953  
[info@biofinechemical.com](mailto:info@biofinechemical.com) - [www.biofinechemical.com](http://www.biofinechemical.com)

#### 1.4. Emergency telephone number

Emergency number : +91 99921 51495 (10.00am - 06.30pm) (Office Hours)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

#### 2.3. Other hazards

Contains no PBT and/or vPvB substances  $\geq$  0.1% assessed in accordance with REACH Annex XIII

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
LACTOSE MONOHYDRATE	CAS-No.: 10039-26-6 EC-No.: 600-087-0	100

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.  
First-aid measures after skin contact : Wash skin with plenty of water.  
First-aid measures after eye contact : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. If eye irritation persists: Get medical advice/attention.  
First-aid measures after ingestion : Rinse mouth out with water. Call a poison center or a doctor if you feel unwell.  
First-aid measures for first aider : First aid workers will be equipped with suitable personal protective equipment.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure. Although no appropriate human or animal health effects data are known to exist, this material is expected to be an inhalation hazard.  
Symptoms/effects after skin contact : None under normal conditions. Dust may cause irritation in skin folds or by contact in combination with tight clothing.  
Symptoms/effects after eye contact : None under normal conditions. Dust from this product may cause eye irritation.  
Symptoms/effects after ingestion : None under normal conditions.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.  
Unsuitable extinguishing media : Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : No fire hazard.  
Explosion hazard : No direct explosion hazard.  
Hazardous decomposition products in case of fire : Toxic fumes may be released.

#### 5.3. Advice for firefighters

Firefighting instructions : Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection.  
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage.
- For non-emergency personnel**
- Protective equipment : Wear recommended personal protective equipment.
- Emergency procedures : Ventilate spillage area. Evacuate unnecessary personnel.
- For emergency responders**
- Protective equipment : Do not attempt to take action without suitable protective equipment. Use personal protective equipment as required. For further information refer to section 8: "Exposure controls/personal protection".
- Emergency procedures : Stop release. Evacuate unnecessary personnel.

#### 6.2. Environmental precautions

Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

- For containment : Using a clean shovel, put the material in a dry container and cover without compressing it.
- Methods for cleaning up : Mechanically recover the product. Clear up rapidly by scoop or vacuum.
- Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.
- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with eyes.
- Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Keep in a cool, well-ventilated place away from heat.
- Storage conditions : Store in original container. Keep container tightly closed. Store in a dry place.
- Packaging materials : Store always product in container of same material as original container.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

Appropriate engineering controls

**Appropriate engineering controls:**

Ensure good ventilation of the work station.

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### Personal protection equipment

#### Personal protective equipment:

Wear recommended personal protective equipment.

#### Personal protective equipment symbol(s):



### Eye and face protection

#### Eye protection:

Chemical goggles or safety glasses

### Skin protection

#### Skin and body protection:

Wear a mask

#### Hand protection:

Protective gloves

### Respiratory protection

#### Respiratory protection:

Wear appropriate mask

### Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White to almost white.
Appearance	: Crystalline powder.
Molecular mass	: 360.31 g/mol
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: 200 – 202 °C
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 357.8 °C
Auto-ignition temperature	: 390 °C
Decomposition temperature	: Not available
pH	: 4 – 6 at 20 °C
pH solution concentration	: 10 %
Viscosity, kinematic	: Not applicable
Solubility	: Water: 161 g/l at 20 °C - soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.525 g/cm <sup>3</sup> at 20 °C
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

No additional information available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

Direct sunlight. Overheating. Open flame. Heat. Sparks.

#### 10.5. Incompatible materials

No additional information available

#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified pH: 4 – 6 at 20 °C
Serious eye damage/irritation	: Not classified pH: 4 – 6 at 20 °C
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

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Viscosity, kinematic	Not applicable

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

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### 12.2. Persistence and degradability

#### LACTOSE MONOHYDRATE EXTRA PURE (10039-26-6)

Persistence and degradability	Rapidly degradable
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### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Comply with applicable regulations for solid waste disposal. Disposal must be done according to official regulations.
Additional information	: Do not re-use empty containers.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

### 14.1. UN number or ID number

Not regulated for transport

### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not regulated
Proper Shipping Name (RID)	: Not regulated

### 14.3. Transport hazard class(es)

**ADR**  
Transport hazard class(es) (ADR) : Not regulated

**IMDG**  
Transport hazard class(es) (IMDG) : Not regulated

**IATA**  
Transport hazard class(es) (IATA) : Not regulated

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### ADN

Transport hazard class(es) (ADN) : Not regulated

### RID

Transport hazard class(es) (RID) : Not regulated

### 14.4. Packing group

Packing group (ADR) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

Packing group (RID) : Not regulated

### 14.5. Environmental hazards

Other information : No supplementary information available

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

##### POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

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### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### National regulations

#### Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV).  
Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

#### Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed  
SZW-lijst van mutagene stoffen : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed  
SZW-lijst van reprotoxische stoffen –  
Vruchtbaarheid : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development



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<b>Abbreviations and acronyms:</b>	
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disruptor

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.