

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 SDS Reference Number: 04330

Issue date: 4/9/2014 Revision date: 9/11/2024 Supersedes version of: 4/9/2015 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance

Trade name : LACTOSE MONOHYDRATE AR

 EC-No.
 : 600-087-0

 CAS-No.
 : 10039-26-6

 Product code
 : 04330

 Type of product
 : Carbohydrate

 Formula
 : C12H22O11 · H2O

Chemical structure

HO OH OH OH OH OH

Synonyms : Milk sugar, D-Lactose Monohydrate, β-D-Gal-(1→4)-D-Glc, 4-O-β-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

LOBA CHEMIE PVT.LTD.

107 Wode House Road, Jehangir Villa, Colaba

400005 Mumbai

INDIA

T +91 22 6663 6663, F +91 22 6663 6699 info@lobachemie.com, www.lobachemie.com

1.4. Emergency telephone number

Emergency number : + 91 22 6663 6663 (9:00am - 6:00 pm)

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 ≥ 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. Give oxygen or artificial

respiration if necessary. If you feel unwell, seek medical advice.

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 : 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.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

Emergency procedures : 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.

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.

: Ensure good ventilation of the work station. Wear personal protective equipment. Protect

from moisture.

Hygiene measures : Always wash hands after handling the product. Do not eat, drink or smoke when using this

product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Keep in a cool, well-ventilated place away from heat.

Storage conditions : Keep cool. Protect from sunlight.

Packaging materials : Store always product in container of same material as original container.

7.3. Specific end use(s)

Precautions for safe handling

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.

Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

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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. : Not available Odour threshold : 200 - 202 °C Melting point Freezing point : Not applicable : Not available Boiling point Flammability : Not available Lower explosion limit : Not applicable : Not applicable Upper explosion limit 357.8 °C Flash point Auto-ignition temperature 390 °C Decomposition temperature Not available рΗ : 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/cm³ at 20 °C
Relative density : Not available
Relative vapour density at 20°C : Not applicable

9.2. Other information

Particle size

No additional information available

: Not 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.

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

: Not classified : Not classified : Not classified Not classified : 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

Respiratory or skin sensitisation

Germ cell mutagenicity

Reproductive toxicity

STOT-single exposure

Carcinogenicity

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. Not classified

Hazardous to the aquatic environment, short-term

(acute)

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified

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12.2. Persistence and degradability

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Persistence and degradability Rapidly degradable

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 – : The substance is not listed

Vruchtbaarheid

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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Abbreviations and acronyms:	
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.