Lactose monohydrate Analytical Grade Ph Eur, BP, NF

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Date of issue: 22/03/2011 Revision date: 12/07/2022 Supersedes version of: 21/05/2018 Version: 2.2

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

1.1. Product identifier

Product form	:	Substance
Trade name	:	Lactose monohydrate Analytical Grade Ph Eur, BP, NF
EC-No.	:	200-559-2
CAS-No.	:	10039-26-6
Product code	:	LACT-01A
Formula	:	C12H22O11.H2O
REACH authorisation exemptions	:	Exempted from REACH registration

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

1.2.1. Relevant identified uses

Main use category : Laboratory use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

labbox labware s.l.
Migjorn, 1
P.O. Box Barcelona (SPAIN)
08338 Premia de Dalt – SPAIN
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T +34 937 07 79 70 - F +34 937 909 532
info@labbox.com - www.labbox.com

1.4. Emergency telephone number

Emergency number : +34 937 077 970 (For technical information_Office Hours) In case of medical emergency phone 112 or to your local emergency number.

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Belfast Centre) Royal Victoria Hospital	Grosvenor Road BT12 6BA	0344 892 0111	

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

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%
Lactose monohydrate	CAS-No.: 10039-26-6 EC-No.: 200-559-2	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Gently wash with plenty of soap and water.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Get medical advice/attention if you feel unwell.

First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Get medical advice/attention if you feel unwell.

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

No additional information available

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Carbon dioxide. Foam. Dry powder.

Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : fume. Carbon dioxide. Carbon monoxide.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Absorb spillage to prevent material damage. Avoid dust formation.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.
Methods for cleaning up : Take up liquid spill into absorbent material.

6.4. Reference to other sections

See Heading 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Hygiene measures : 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 a well-ventilated place. Keep container tightly closed.
Storage area : Store away from heat.
Special rules on packaging : Store in a closed container. Keep only in original container.

7.3. Specific end use(s)

Laboratory chemicals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Lactose monohydrate Analytical Grade Ph Eur, BP, NF (10039-26-6)	
France - Occupational Exposure Limits	
Local name	Saccharose
VME (OEL TWA)	10 mg/m³
Remark	Valeurs recommandées/admises
Portugal - Occupational Exposure Limits	
Local name	Sacarose
OEL TWA	10 mg/m³
Spain - Occupational Exposure Limits	
Local name	Sacarosa
VLA-ED (OEL TWA) [1]	10 mg/m³
United Kingdom - Occupational Exposure Limits	
Local name	Sucrose
WEL TWA [1]	10 mg/m³
WEL STEL	20 mg/m³

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:
EN 374.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:
Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
Wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:
The present safety data sheet is consistent with the specific conditions relied on to justify the registration of the substance as isolated intermediate.
Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	white.
Odour	:	odourless.
Odour threshold	:	Not available
Melting point	:	223 °C
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive properties	:	Product is not explosive.
Explosive limits	:	Not applicable
Lower explosion limit	:	60 g/m³
Upper explosion limit	:	Not applicable
Flash point	:	

Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	4 – 6
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50 °C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20 °C	:	Not applicable
Particle size	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Bulk density : 500 kg/m³

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5. Incompatible materials

Acids. Oxidizing agent.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

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
Serious eye damage/irritation	:	Not classified pH: 4 – 6
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

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	:	Not classified
Hazardous to the aquatic environment, long-term (chronic)	:	Not classified

12.2. Persistence and degradability

No additional information available

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 legislation (waste)	:	Disposal must be done according to official regulations.
Waste treatment methods	:	Must follow special treatment according to local regulation.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR)	:	Not regulated
UN-No. (IMDG)	:	Not regulated
UN-No. (IATA)	:	Not regulated
UN-No. (ADN)	:	Not regulated
UN-No. (RID)	:	Not regulated

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

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

Dangerous for the environment : No
Marine pollutant : No
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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

No REACH Annex XVII restrictions

REACH Annex XIV (Authorisation List)

Lactose monohydrate Analytical Grade Ph Eur, BP, NF is not on the REACH Annex XIV List

REACH Candidate List (SVHC)

Lactose monohydrate Analytical Grade Ph Eur, BP, NF is not on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Lactose monohydrate Analytical Grade Ph Eur, BP, NF is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals.

POP Regulation (Persistent Organic Pollutants)

Lactose monohydrate Analytical Grade Ph Eur, BP, NF is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Ozone Regulation (1005/2009)

Lactose monohydrate is not subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Explosives Precursors Regulation (2019/1148)

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Drug Precursors Regulation (273/2004)

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Water hazard class (WGK)	:	Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of 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
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	The substance is not listed

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

No additional information available

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.