



Safety Data Sheet

Lactose monohydrate

Section 1: Chemical Product and Company Identification

Product Name: Lactose monohydrate

Catalog Codes: 503

CAS#: 10039-26-6

RTECS: -

Synonym: Milk sugar, Lactobiose

Chemical Name: Lactose monohydrate

Chemical Formula: $C_{12}H_{22}O_{11} \cdot H_2O$

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Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Lactose monohydrate	10039-26-6	100

Toxicological Data on Ingredients: LD50 Oral - Rat - > 10.000 mg/kg

Section 3: Hazards Identification

Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

Label elements

Not a hazardous substance or mixture.

Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic

(PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Section 4: First Aid Measures

Description of first-aid measures

If inhaled

After inhalation: fresh air

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 3) and/or in section 11

Indication of any immediate medical attention and special treatment needed

No data available

Section 5: Fire and Explosion Data

Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder.

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

Special hazards arising from the substance or mixture

Carbon oxides

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.
For personal protection see section 8.

Environmental precautions

Do not let product enter drains.

Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

Reference to other sections

For disposal see section 13.

Section 7: Handling and Storage

Precautions for safe handling

For precautions see section 3.

Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Recommended storage temperature see product label.

Section 8: Exposure Controls/Personal Protection

Control parameters

Ingredients with workplace control parameters

Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other

substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

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Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P1

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

a) Physical state	solid Color: white
b) Color	No data available
c) Odor	No data available
d) Melting point/freezing point	202 °C
e) Initial boiling point and boiling range	No data available

f) Flammability (solid, gas)	May form combustible dust concentrations in air.
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	No data available
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available
k) pH	4.0 - 6.5(H ₂ O, 20 °C)
l) Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m) Water solubility	No data available
n) Partition coefficient: n-octanol/water	No data available
o) Vapor pressure	No data available
p) Density	No data available
Relative density	No data available
q) Relative vapor density	No data available
r) Particle characteristics	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available
Other safety information	
Bulk density	ca.500 kg/m ³

Section 10: Stability and Reactivity Data

Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

Possibility of hazardous reactions

Violent reactions possible with:
Strong oxidizing agents

Conditions to avoid

no information available

Incompatible materials

No data available

Hazardous decomposition products

In the event of fire: see section 5

Section 11: Toxicological Information

Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - > 10.000 mg/kg

Remarks:

(anhydrous substance)

(RTECS)

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Carcinogenicity

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Specific target organ toxicity - single exposure

Specific target organ toxicity - repeated exposure

Aspiration hazard

Additional Information

Not availableNo

Section 12: Ecological Information**Toxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects

No data available

Section 13: Disposal Considerations**Waste treatment methods****Product**

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself

Section 14: Transport Information

UN number

ADR/RID: -

IMDG: -

IATA: -

UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

Packaging group

ADR/RID: -

IMDG: -

IATA: -

Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

Special precautions for user**Further information**

Not classified as dangerous in the meaning of transport regulations.

Section 15: Other Regulatory Information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

National legislation

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

Section 16: Other Information

References: Not available

Other Special Considerations: Not available

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