

Lactose monohydrate

Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 11/05/2012 Revision date 14/03/2018

L1372

Version: 2.0

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

1.1. Product identifier

Product form	: Substance
Trade name	: Lactose monohydrate
IUPAC name	: β -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucose
EC-No.	: 200-559-2
CAS-No.	: 10039-26-6
Product code	: L1372
Formula	: C ₁₂ H ₂₂ O ₁₁ · H ₂ O
Synonyms	: Lactobiose Milk sugar 4-O- β -D-galactopyranosyl-D-glucose
Product group	: Raw material
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	: Professional use
Industrial/Professional use spec	: For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.
Function or use category	: Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Biochemie B.V.
A. Hofmanweg 71
2031 BH Haarlem - The Netherlands
T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

1.4. Emergency telephone number

Emergency number	: Supplier contact information: +31(0)23-5319093 (M-F 09:00-17:00) +31(0)6-30109355 (outside office hours)
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Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/	Consult website for a local poison centre

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

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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

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing
Get medical advice and attention if you feel unwell.

First-aid measures after skin contact : Wash skin with mild soap and water.

First-aid measures after eye contact : Rinse immediately with plenty of water
If eye irritation persists, take medical advice.

First-aid measures after ingestion : Rinse mouth.
Drink plenty of water
If you feel unwell, seek medical advice.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : This product is flammable. On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide.
- Explosion hazard : Large amounts: Risk of dust explosion.

5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.
- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Avoid raising dust. Ensure adequate air ventilation.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment.

6.2. Environmental precautions

- Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water. Detergent.

6.4. Reference to other sections

- No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- No additional information available

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from moisture.
- Maximum storage period : 5 year

7.3. Specific end use(s)

- For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- No additional information available

8.2. Exposure controls

Hand protection:

- No specific measures are necessary

Eye protection:

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Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Not required

Respiratory protection:

Where excessive dust may result, wear approved mask. Type P1 (EN 143)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 360,3 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
pH solution	: 100 (4 - 6,5) g/l in H ₂ O, 20°C
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 200 - 225 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: 420 - 450 °C
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 330 - 770 kg/m ³ depends on particle size
Solubility	: Soluble in water. Water: ≈ 16,1 % 20 °C
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 60 - 125 g/m ³

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

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10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Lactose monohydrate (10039-26-6)	
LD50 oral rat	> 10000 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

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

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

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

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12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
14.1. UN number		
Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not regulated

- Transport by sea

Not regulated

- Air transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

No REACH Annex XVII restrictions

Lactose monohydrate is not on the REACH Candidate List

Lactose monohydrate is not on the REACH Annex XIV List

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15.1.2. National regulations

Ensure all national/local regulations are observed.

Germany

12th Ordinance Implementing the Federal Immission Control Act -
12.BImSchV

: Is not subject of the 12. BImSchV
(Hazardous Incident Ordinance)

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 chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
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Abbreviations and acronyms:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
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
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL of 16 December 2008 on classification, labelling
and packaging of substances and mixtures, amending and repealing
Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No
1907/2006.

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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