

# SAFETY DATA SHEET

Version 8.5  
Revision Date 2025.11.24  
Print Date 2025.11.25

## 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifiers

Product name : D-Lactose monohydrate

Product Number : 61339

Brand : Sigma

### 1.2 Other means of identification

$\beta$ -D-Gal-(1 $\rightarrow$ 4)-D-Glc

Milk sugar

4-O- $\beta$ -D-Galactopyranosyl-D-glucose

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

Identified uses : For R&D use only. Not for pharmaceutical, household or other uses.

### 1.4 Details of the supplier of the safety data sheet

Company :

MERCK LTD.  
20F., No. 121, Jingmao 2nd Road, Nangang District, Taipei City  
115, Taiwan

Merck KGaA  
64271 Darmstadt  
Germany  
Phone: +49 6151 72-0

### 1.5 Emergency telephone number

Emergency Phone : +(44)-870-8200418 (CHEMTREC (GB))  
Number : +(353)-19014670 (CHEMTREC Ireland)  
001-803-017-9114 (CHEMTREC India)

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## 2. HAZARDS IDENTIFICATION

### GHS Classification

Not a hazardous substance or mixture according to CNS 15030: Classification and labeling of chemicals (GHS 2011)

### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

### Other hazards which do not result in classification

May form explosible dust-air mixture if dispersed.

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

CAS-No. : 64044-51-5

### Components

No hazardous ingredients

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## 4. FIRST AID MEASURES

### First aid measures for different exposure routes

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 2.2) and/or in section 11

Protection of first-aiders : For personal protection see section 8.

Notes to physician : No data available

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## 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water  
Foam

Carbon dioxide (CO<sub>2</sub>)  
Dry powder

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

Specific hazards during fire fighting : Combustible.

Risk of dust explosion.

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

Hazardous combustion products : Carbon oxides

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

Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.

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## 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.  
Advice for emergency responders:  
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.

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## 7. HANDLING AND STORAGE

### Handling

For precautions see section 2.2.

Advice on protection against fire and explosion : Keep away from open flames, hot surfaces and sources of ignition.  
Take precautionary measures against static discharge.

### Storage

Further information on storage conditions : Tightly closed.  
Dry.

Storage class : 11, Combustible Solids

Recommended storage temperature : Recommended storage temperature see product label.

Further information on storage stability : hygroscopic

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

### Biological occupational exposure limits

Contains no substances with biological exposure indices.

**Engineering measures** : No data available

### Personal protective equipment

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.

Eye protection : Use equipment for eye protection tested and ap-

proved under appropriate government standards such as NIOSH (US) or EN 166(EU).  
Safety glasses

Hygiene measures : Change contaminated clothing. Wash hands after working with substance.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Color : No data available

Odor : No data available

Odor Threshold : No data available  
pH : No data available

Melting point : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form combustible dust concentrations in air.

Flammability (liquids) : No data available

Burning rate : No data available

Upper explosion limit /  
Upper flammability limit : No data available

Lower explosion limit /  
Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Water solubility : No data available

Partition coefficient: n-  
octanol/water : No data available

Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Flow time	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Molecular weight	: 360.31 g/mol
Particle characteristics	
Particle size	: No data available

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## 10. STABILITY AND REACTIVITY

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	: Strong oxidizing agents
Hazardous decomposition products	: In the event of fire: see section 5

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## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

Oral: No data available

Inhalation: No data available

Dermal: No data available

#### Skin corrosion/irritation

Remarks: No data available

**Serious eye damage/eye irritation**

Remarks: No data available

**Respiratory or skin sensitization**

No data available

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

No data available

**Reproductive toxicity**

No data available

**Specific target organ toxicity - single exposure**

No data available

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

**11.2 Additional Information**

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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**12. ECOLOGICAL INFORMATION****Ecotoxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : 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.

The chemical must be disposed or recycled in accordance with Waste Disposal Act. See [www.epa.gov.tw](http://www.epa.gov.tw) for the information of chemical waste disposal companies and their contacts.

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## 14. TRANSPORT INFORMATION

### International Regulations

#### IATA-DGR

Not regulated as a dangerous good

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

#### IMDG-Code

Not regulated as a dangerous good

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : no

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

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## 15. REGULATORY INFORMATION

### National regulatory information

Occupational Safety and Health Act; Regulations on Occupational Safety and Health Facilities : applicable  
Waste Disposal Act; Standards for the Storage, Cleanup, Handling and Disposal of Industrial Waste : applicable  
Regulations on Labelling and Hazard Communication of Hazardous Chemicals; Exposure Assessment : Not classified as dangerous or harmful substances

Assessment and Control Banding of Hazardous Chemicals	: Not applicable
Rules on Road Traffic Safety	: Not applicable
Standards of Permissible Exposure Limits in Workplace	: Contains no substances with occupational exposure limit values.
Rules on the Prevention of Poisoning from Organic Solvents.	: Not applicable
Standard for the Control of Designated Hazardous and Dangerous Chemicals	: Not applicable
Standards for Establishing Places for Manufacturing, Storing, Processing Public Hazardous Substances and Flammable Pressurized Gases, and Regulations on Safety Control of such Places	: Not applicable
Toxic and Concerned Chemical Substances Control Act	
Toxic chemical substances	: Not applicable
Concerned chemical substances	: Not applicable
Regulations for Governing Designating and Handling of Priority Management Chemicals	: Not applicable
Rules on Labour Health Protection	: Not applicable

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## 16. OTHER INFORMATION

### Further information

Literature references	: About detail information, please refer to each section. The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.
Organization that prepared the SDS	: Name: Merck KGaA LS-QH Address/Telephone number: 64271 Darmstadt Germany/+49 6151 72-0
Date that the SDS was prepared	: 2025.11.24
Other information	: The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See <a href="http://www.sigma-aldrich.com">www.sigma-aldrich.com</a> and/or the reverse side of invoice or packing slip for additional terms and condi-

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Date format : yyyy/mm/dd

### **Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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