

# LACTITOL MONOHYDRATE CRS

## Safety Data Sheet

Safety Data Sheet in accordance to Regulation (EC) No. 1907/2006, as amended.

Date of issue: 27/06/2013

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Version: 6.0

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

#### 1.1. Product identifier

Product form : Substance  
Trade name : LACTITOL MONOHYDRATE CRS  
CAS No : 81025-04-9  
Product code : L0129000

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

##### 1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.  
Use of the substance/mixture : For professional use only  
Function or use category : Laboratory chemicals

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
F-67081 Strasbourg  
T +33(0)388412035 - F +33(0)388412771

#### 1.4. Emergency telephone number

Emergency number : +44(0)1235239670

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Not classified

##### Classification according to Directive 67/548/EEC or 1999/45/EC

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

Other hazards not contributing to the classification : Exposure may produce an allergic reaction.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
LACTITOL MONOHYDRATE (Main constituent)	(CAS No)81025-04-9	≤ 100	Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
LACTITOL MONOHYDRATE (Main constituent)	(CAS No)81025-04-9	≤ 100	Not classified

Full text of R-, H- and EUH-phrases: see section 16

#### 3.2. Mixture

Not applicable

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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : Move to fresh air.  
First-aid measures after skin contact : Rinse with water.  
First-aid measures after eye contact : Rinse eyes with water as a precaution.

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

Symptoms/injuries : None known.

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

In all cases of doubt, or when symptoms persist, seek medical attention.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Small amounts: Use extinguishing media appropriate for surrounding fire. Water spray. Carbon dioxide. Dry powder. Foam. Large amounts: Not applicable.

#### 5.2. Special hazards arising from the substance or mixture

Reactivity : Stable under normal conditions.

#### 5.3. Advice for firefighters

Precautionary measures fire : Small amounts: Use normal individual fire protective equipment. Large amounts: Not applicable.  
Firefighting instructions : Dilute with water.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid raising dust. Avoid all unnecessary exposure. Large amounts: Not applicable.

##### 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

No additional information available

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Clean thoroughly. Clean with water.

#### 6.4. Reference to other sections

No additional information available

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : To guarantee the quality and properties of the product, keep : dry, Keep in a cool, well-ventilated place away from heat. Store in original container.  
Incompatible products : Strong oxidizing agents.

#### 7.3. Specific end use(s)

See Heading 1.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

No additional information available

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder. white. Powder.
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: 4,7 - 7 (10%)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 95 - 98 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 100 °C
Self ignition temperature	: No data available
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
Solubility	: Water: ≥ 1 mg/l
Log Pow	: -5,53 at 20°C
Log Kow	: 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	: No data available

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions.

#### 10.2. Chemical stability

No additional information available

#### 10.3. Possibility of hazardous reactions

Small amounts: None known. Large amounts: Not applicable.

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

Small amounts: None under normal use. Large amounts: Not applicable.

#### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes. Large amounts: Not applicable.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Not classified

#### LACTITOL MONOHYDRATE CRS(81025-04-9)

LD50 oral rat	> 30000 mg/kg
Skin corrosion/irritation	: Not classified pH: 4,7 - 7 (10%)
Serious eye damage/irritation	: Not classified pH: 4,7 - 7 (10%)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified

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Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: To our knowledge, the product does not present any particular risk, under normal conditions of use. Large amounts: Not applicable.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Small amounts: Presents no specific risk for the environment. Large amounts: Not applicable.
Ecology - water	: Soluble in water.

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

LACTITOL MONOHYDRATE CRS(81025-04-9)	
Log Pow	-5,53 at 20°C
Bioaccumulative potential	Weak.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA

### 14.1. UN number

No dangerous good in sense of transport regulations

### 14.2. UN proper shipping name

Not applicable

### 14.3. Transport hazard class(es)

Not applicable

### 14.4. Packing group

Not applicable

### 14.5. Environmental hazards

Other information : No supplementary information available.

### 14.6. Special precautions for user

#### 14.6.1. Overland transport

No additional information available

#### 14.6.2. Transport by sea

No additional information available

#### 14.6.3. Air transport

No additional information available

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

Not applicable

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### 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

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other information

SDS EU (REACH Annex II)

*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*