

# Mannitol

## Safety Data Sheet

**255114 / 1099175**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 27/05/2013 Revision date: 21/03/2017

Supersedes 01/10/2014

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

### 1.1. Product identifier

Product form : Substance  
Substance name : Mannitol  
EC-No. : 2007118  
CAS-No. : 69-65-8  
Product code : 255114 / 1099175  
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

Industrial/Professional use spec : Industrial  
For professional use only

#### 1.2.2. Uses advised against

No additional information available

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

#### Supplier

Duchefa Farma BV  
A. Hofmanweg 71  
2031BH Haarlem - The Netherlands  
T +31(0)23-5319093  
[farma@ducheffa.nl](mailto:farma@ducheffa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

### 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)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

## 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

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

**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**

Substance type : Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Mannitol	(CAS-No.) 69-65-8 (EC-No.) 2007118	100	Not classified

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 general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

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

- Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

**SECTION 5: Fire-fighting measures****5.1. Extinguishing media**

- Suitable extinguishing media : All extinguishing agents can be used.
- Unsuitable extinguishing media : Do not use a heavy water stream.

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

- Fire hazard : Combustible.

### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. 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

- General measures : Avoid contact with skin and eyes. Do not breathe dust.

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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

- Methods for cleaning up : Store away from other materials. On land, sweep or shovel into suitable containers. Minimize generation of dust.

### 6.4. Reference to other sections

Reference to other sections (8, 13).

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.

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

- Storage conditions : Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use. Store in a dry place.
- Incompatible products : solvents.
- Incompatible materials : Sources of ignition. Direct sunlight.
- Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

Pharmaceutical industry.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

**8.2. Exposure controls****Personal protective equipment:**

Avoid all unnecessary exposure.

**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

**Eye protection:**

Where excessive dust may result, wear goggles

**Respiratory protection:**

No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

**Other information:**

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	: No data available
pH	: 5 - 7
pH solution	: 100 g/l 20 ° C
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 165 - 168 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 400 - 500 kg/cbm
Solubility	: Water. Water: 200 g/l 20 ° C
Log Pow	: -3.1
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

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

**9.2. Other information**

No additional information available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

Combustible. Dust clouds can be explosive.

**10.2. Chemical stability**

Not established.

**10.3. Possibility of hazardous reactions**

Not established.

**10.4. Conditions to avoid**

Not established. Extremely high or low temperatures.

**10.5. Incompatible materials**

Strong oxidizers.

**10.6. Hazardous decomposition products**Carbon oxides (CO, CO<sub>2</sub>).**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

Acute toxicity : Not hazardous

Mannitol (69-65-8)	
LD50 oral rat	13500 mg/kg

Skin corrosion/irritation : Not classified  
pH: 5 - 7

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified  
pH: 5 - 7

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified  
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information****12.1. Toxicity**

Ecology - general : Readily biodegradable.

**12.2. Persistence and degradability**

Mannitol (69-65-8)	
Persistence and degradability	Readily biodegradable.
ThOD	1.15 g O <sub>2</sub> /g substance
BOD (% of ThOD)	87 % ThOD

**12.3. Bioaccumulative potential**

Mannitol (69-65-8)	
Log Pow	-3.1
Bioaccumulative potential	Not established.

**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**

Additional information : Avoid release to the environment

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Regional legislation (waste) : Disposal must be done according to official regulations.  
Waste treatment methods : Small amounts: Household refuse.  
Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.

**SECTION 14: Transport information**

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

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

**14.6. Special precautions for user****- Overland transport**

No data available

**- Air transport**

No data available

**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

Mannitol is not on the REACH Candidate List

Mannitol is not on the REACH Annex XIV List

**15.1.2. National regulations**

No additional information available

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**

Indication of changes:

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.

1.4	Emergency telephone	Modified	Added additional information
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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.

Other information

: REACH Disclaimer:

This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

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