

# Sorbitol liquid crystallising (70%)

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 02/03/2015 Revision date: 18/04/2017

**604305**

Version: 2.0

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

### 1.1. Product identifier

Product form : Mixtures  
Product name : Sorbitol liquid crystallising (70%)  
CAS-No. : 50-70-4 (D-Glucitol)  
Product code : 604305  
Product group : Raw material  
Other means of identification : Aqueous solution of a hydrogenated, partly hydrolysed starch

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

#### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry  
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@duchefa.nl](mailto:farma@duchefa.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

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604305

## Safety Data Sheet

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

### 2.2. Label elements

According to EC directives or the corresponding national regulations there is no labelling obligation for this product.

### 2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sorbitol	(CAS-No.) 50-70-4 (EC-No.) 200-061-5	~ 70	Not classified
Aqua	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	~ 30	Not classified

Full text of H-statements: see section 16

## 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. Give water to drink. If you feel unwell, seek medical advice.

### 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.
Symptoms/effects after ingestion	: Diarrhea.

### 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 : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

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

Hazardous decomposition products in case of fire : In case of fire hazardous gases / vapors may form: flue gas.

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604305

## Safety Data Sheet

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

### 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 : Do not breathe gas/fumes/vapour/spray.

#### 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 : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

### 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 container closed when not in use. Keep only in the original container in a cool, well-ventilated place.
- Incompatible products : Strong bases. Strong acids.
- 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

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604305

## 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:

Safety glasses (to European standard EN 166 or equivalent)

#### 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	: Liquid
Appearance	: Viscous.
Colour	: Colourless.
Odour	: odourless.
Odour threshold	: No data available
pH	: 6
pH solution	: 50 %
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
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	: <
Relative density	: No data available
Density	: 1.3 g/cm <sup>3</sup>
Solubility	: completely miscible with water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: 210 Pa.s
Explosive properties	: not explosive.
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

No additional information available

#### 10.2. Chemical stability

Not established.

#### 10.3. Possibility of hazardous reactions

Not established.

#### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

#### 10.5. Incompatible materials

Strong acids. Strong bases.

#### 10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified pH: 6
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified pH: 6
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

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Viscosity, kinematic	161538.46153846 mm <sup>2</sup> /s
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Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

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### SECTION 12: Ecological information

#### 12.1. Toxicity

No additional information available

#### 12.2. Persistence and degradability

Sorbitol liquid crystallising (70%) (50-70-4 (D-Glucitol))	
Persistence and degradability	Not established.

#### 12.3. Bioaccumulative potential

Sorbitol liquid crystallising (70%) (50-70-4 (D-Glucitol))	
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

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

#### 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**

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

**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:

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

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
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
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
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
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
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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SDS EU (REACH Annex II) Version 2017

*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*