



# SORBITOL 70% PHARMA

## Product Safety Information Sheet

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

SDS Ref.: SORBITOL

Issue date: 7/6/2020 Revision date: 7/6/2020 Supersedes: 3/5/2014 Version: 4.0

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

### 1.1. Product identifier

Product form : Substance  
Substance name : SORBITOL 70% PHARMA  
EC-No. : 270-337-8  
CAS-No. : 68425-17-2 / 1259528-21-6  
REACH registration No : 01-21194935576-23  
Product code : SORBITOL

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

#### 1.2.1. Relevant identified uses

Use of the substance/mixture : food, pharma, cosmetic, textile

#### 1.2.2. Uses advised against

No additional information available

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

INTERCHIMIE  
ZAC du Parc  
13 rue Louis Blériot  
FR- 77290 COMPANS  
T T: +33 (0)1 64 77 76 27  
[qualite@interchimie.fr](mailto:qualite@interchimie.fr) - [www.interchimie.fr](http://www.interchimie.fr)

### 1.4. Emergency telephone number

No additional information available

## 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

### 2.2. Label elements

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

No labelling applicable

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

CAS-No. : 68425-17-2 / 1259528-21-6  
EC-No. : 270-337-8

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Name	Product identifier	%
Hydrolysát amidon hydrogéné	(CAS-No.) 68425-17-2 / 1259528-21-6 (EC-No.) 270-337-8 (REACH-no) 01-2119493576-23	≥ 100

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: This product is not considered to be hazardous.
First-aid measures after inhalation	: If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash with soapy water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: This product is not considered to be hazardous. Get medical advice/attention 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.
Symptoms/effects after ingestion	: Diarrhea.

### 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. Water spray. Foam. Dry powder. Sand.
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### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide.
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### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment.
Other information	: Prevent fire fighting water from entering the environment.

## SECTION 6: Accidental release measures

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

General measures	: Spill area may be slippery. Evacuate area.
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#### 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

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

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

Methods for cleaning up	: Take up liquid spill into absorbent material.
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### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of solid materials or residues refer to section 13 : "Disposal considerations".

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : This product is not considered to be hazardous.  
Hygiene measures : Always wash hands after handling the product.

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

Incompatible products : Oxidizing agent.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### SORBITOL 70% PHARMA (68425-17-2 / 1259528-21-6)

##### DNEL/DMEL (Workers)

Long-term - systemic effects, dermal	2000 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	5 mg/m <sup>3</sup>

##### DNEL/DMEL (General population)

Long-term - systemic effects, oral	200 mg/kg bw/day
Long-term - systemic effects, dermal	2000 mg/kg bw/day
Long-term - local effects, inhalation	0.89 mg/m <sup>3</sup>

##### PNEC (Water)

PNEC aqua (freshwater)	0.973 mg/l
PNEC aqua (marine water)	0.0973 mg/l
PNEC aqua (intermittent, freshwater)	9.73 mg/l

##### PNEC (Sediment)

PNEC sediment (freshwater)	3.63 mg/kg dwt
PNEC sediment (marine water)	0.363 mg/kg dwt

##### PNEC (Soil)

PNEC soil	0.15 mg/kg dwt
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##### PNEC (STP)

PNEC sewage treatment plant	66.7 mg/l
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### 8.2. Exposure controls

No additional information available

## SECTION 9: Physical and chemical properties

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

Physical state : Liquid

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Appearance	: Viscous liquid.
Colour	: Colourless. light yellow.
Odour	: Neutral.
Odour threshold	: No data available
pH	: No data available
pH solution	: $\approx 50 (\geq 6) \%$
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: $> 100 \text{ }^\circ\text{C}$
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: $\approx 200 \text{ }^\circ\text{C}$
Flammability (solid, gas)	: No data available
Vapour pressure	: $< 12.1 \text{ hPa}$
Relative vapour density at 20 °C	: $\approx 1.3 \text{ g/cm}^3$
Relative density	: No data available
Solubility	: Soluble in water.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: $\approx 400 \text{ mPa}\cdot\text{s} (20^\circ\text{C})$
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

Specific conductivity :  $\approx 60 \text{ }\mu\text{S/m}$

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is stable at normal handling and storage conditions.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Stable under normal conditions of use.

### 10.4. Conditions to avoid

Peut précipiter ou se gélifier à des basses températures.

### 10.5. Incompatible materials

Oxidizing. Oxidizing agent.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. fume.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

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### SORBITOL 70% PHARMA (68425-17-2 / 1259528-21-6)

LD50 oral rat	> 5000 mg/kg
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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
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STOT-single exposure	: Not classified
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STOT-repeated exposure	: Not classified
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Aspiration hazard	: Not classified
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## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

### SORBITOL 70% PHARMA (68425-17-2 / 1259528-21-6)

LC50 fish 1	> 1500 mg/l 96h - oryzias latipes
EC50 Daphnia 1	> 1450 mg/l 48h- Daphnia magna
EC50 72h algae (1)	> 1490 mg/l 72h - Pseudokirchneriella subcapitata

### 12.2. Persistence and degradability

### SORBITOL 70% PHARMA (68425-17-2 / 1259528-21-6)

Persistence and degradability	Biodegradable.
Chemical oxygen demand (COD)	1140 g O <sub>2</sub> /g substance
Biodegradation	73 % 28 jours

### 12.3. Bioaccumulative potential

### SORBITOL 70% PHARMA (68425-17-2 / 1259528-21-6)

Bioaccumulative potential	Low bioaccumulation potential.
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### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

### SORBITOL 70% PHARMA (68425-17-2 / 1259528-21-6)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

## SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	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

#### Inland waterway transport

Not regulated

#### Rail 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

SORBITOL 70% PHARMA is not on the REACH Candidate List

SORBITOL 70% PHARMA is not on the REACH Annex XIV List

SORBITOL 70% PHARMA is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

SORBITOL 70% PHARMA is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

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### 15.1.2. National regulations

#### Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)

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

#### Netherlands

SZW-lijst van kankerverwekkende stoffen : SORBITOL 70% PHARMA is listed

SZW-lijst van mutagene stoffen : SORBITOL 70% PHARMA is 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

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

### 15.2. Chemical safety assessment

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

## SECTION 16: Other information

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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.