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

1.1. Product identifier

Product form: Mixture
Trade name: Sorbitol Special™ Sorbitol Sorbitan Solution, NF
Sorbitol Special™ Sorbitol, Liquid, Partially Dehydrated Ph. Eur.
Sorbitol Special™ GC Sorbitol Sorbitan Solution, NF

SDS code: E-101
Product group: Trade product

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

1.2.1. Relevant identified uses
Use of the substance/preparation: Food/pharmaceutical products.

1.2.2. Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet

SPI Pharma
Chemin du Vallon du Marie
Septemes - France
T 33 4 91 96 36 00 - F 33 4 91 65 39 03
CBlasquez@spipharma.com

1.4. Emergency telephone number

Emergency number: +33 4 91 96 36 00 (Not 24 hrs, business hours only)

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

This substance/mixture does not meet the PBT criteria of REACH, annex XIII.
This substance/mixture does not meet the vPvB criteria of REACH, annex XIII.
other hazards which do not result in classification:
overexposure may produce some discomfort and gastrointestinal disturbances but symptoms are reversible and usually disappear when exposure stops. Repeated or prolonged contact may cause slight irritation to the skin.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Directive 67/548/EEC</th>
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<tbody>
<tr>
<td>Sorbitol</td>
<td>(CAS No.) 50-70-4</td>
<td>44 - 55</td>
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<tr>
<td></td>
<td>(EC no.) 200-061-5</td>
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<tr>
<td>1,4-Anhydro-D-glucitol</td>
<td>(CAS No.) 27299-12-3</td>
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<td></td>
<td>(EC no.) 248-391-9</td>
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<tr>
<td>Water</td>
<td>(CAS No.) 7732-18-5</td>
<td>23</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no.) 231-791-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-Mannitol</td>
<td>(CAS No.) 69-65-8</td>
<td>3 - 4</td>
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<tr>
<td></td>
<td>(EC no.) 292-711-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: In case of accident by inhalation: remove casualty to fresh air and keep at rest. If exposure symptoms persist, seek medical attention.

First-aid measures after skin contact: After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact: Immediately flush eyes thoroughly with water for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion: If a large quantity has been ingested: Immediately get medical attention. Do not induce vomiting unless directed to do so by medical personnel.

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

Symptoms/injuries after inhalation: None known.

Symptoms/injuries after skin contact: Repeated or prolonged contact may cause slight irritation to the skin.

Symptoms/injuries after eye contact: Direct contact with the eyes is likely irritating.

Symptoms/injuries after ingestion: Ingestion of large amounts may produce gastrointestinal disturbances.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard: Product is an aqueous solution which will not burn.

Explosion hazard: None known.

Reactivity: None known.

5.3. Advice for firefighters


SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment: Wear suitable protective clothing gloves, and eye/face protection.

Emergency procedures: Take up liquid spill into inert absorbent material.

6.1.2. For emergency responders

Protective equipment: Wear suitable protective clothing, gloves and eye/face protection.

Emergency procedures: Take up liquid spill into inert absorbent material, e.g.: sand/earth.

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

For containment: Contain the discharged material.

Methods for cleaning up: No special procedures required.

6.4. Reference to other sections

Refer to sections 8 and 13.
SECTION 7: Handling and storage

7.1. Precautions for safe handling
Precautions for safe handling: Avoid repeated or prolonged skin contact. Avoid contact with eyes.
Hygiene measures: Wash hands thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage condition(s): Keep container tightly closed. Store at room temperature.

7.3. Specific end use(s)
No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
No additional information available

8.2. Exposure controls
Appropriate engineering controls: Provide local exhaust or general room ventilation to minimize vapour concentrations.
Personal protective equipment: Gloves. Safety glasses.
Hand protection: Wear impervious gloves for prolonged contact.
Eye protection: Safety glasses with side-shields.
Respiratory protection: In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state: Liquid
Appearance: Clear, viscous liquid.
Colour: Colorless.
Odour: None.
Odour threshold: No data available
pH: ca. 7
Melting point: No data available
Solidification point: No data available
Boiling point: > 100 °C
Flash point: Not applicable
Relative evaporation rate (butylacetate=1): No data available
Flammability (solid, gas): No data available
Explosive limits: Not applicable vol %
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: No data available
Solubility: Soluble in water.
Log Pow: No data available
Log Kow: No data available
Self ignition temperature: No data available
Decomposition temperature: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: ca. 280 cP at 25°C
Explosive properties: No data available
Oxidising properties: No data available

9.2. Other information
No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity
None known.
10.2. Chemical stability
Stable.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
Incompatible materials.

10.5. Incompatible materials
None known.

10.6. Hazardous decomposition products
Carbon oxides (CO, CO₂), low molecular weight hydrocarbons.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Acute toxicity</th>
<th>Not classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD₅₀ oral rat</td>
<td>15900 mg/kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skin corrosion/irritation</th>
<th>Not classified (Conclusive but not sufficient for classification) pH: ca. 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified (Conclusive but not sufficient for classification) pH: ca. 7</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified (none of the components is classified for respiratory or skin sensitization)</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified (No classification for mutagenicity as none of the components is classified for mutagenicity)</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified (No classification for carcinogenicity as none of the components is classified for carcinogenicity)</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified (No classification for reproduction as none of the components is toxic for reproduction)</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Not classified (None of the components shows specific effects in acute toxicity studies requiring classification for Specific Target Organ Systemic Toxicity single exposure)</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Not classified (None of the components shows specific effects in acute toxicity studies requiring classification for Specific Target Organ Systemic Toxicity repeated exposure)</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
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</tbody>
</table>

SECTION 12: Ecological information

12.1. Toxicity
No additional information available

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Sorbitol Special™ Sorbitol Sorbitan Solution</th>
<th>Persistence and degradability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available.</td>
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</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Sorbitol Special™ Sorbitol Sorbitan Solution</th>
<th>Bioaccumulative potential</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available.</td>
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</table>

12.4. Mobility in soil

<table>
<thead>
<tr>
<th>Sorbitol Special™ Sorbitol Sorbitan Solution</th>
<th>Ecology · soil</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available.</td>
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</tbody>
</table>

12.5. Results of PBT and vPvB assessment

<table>
<thead>
<tr>
<th>Sorbitol Special™ Sorbitol Sorbitan Solution</th>
<th>This substance/mixture does not meet the PBT criteria of REACH, annex XIII.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>This substance/mixture does not meet the vPvB criteria of REACH, annex XIII.</td>
</tr>
</tbody>
</table>

12.6. Other adverse effects

| Other information | No data available. |
SECTION 13: Disposal considerations

13.1. Waste treatment methods
Regional legislation (waste): Dispose of contents/container to comply with applicable local, national and international regulations. Disposal must be done according to official regulations.
Additional information: Do not distribute, make available, furnish or reuse empty container.

SECTION 14: Transport information
Not a dangerous good in sense of transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations
No Annex XVII restrictions
Contains no REACH candidate substance

15.1.2. National regulations
No additional information available

15.2. Chemical safety assessment
CSA has not been established

SECTION 16: Other information

Indication of changes: Product name, SDS code, company address and composition of product were updated.
Sources of Key data: MSDS.

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.