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

1.1. Product identifier
Chemical type: Substance
Name: ADVANTOSE™ 100 Crystalline Maltose NF (Monohydrate)
CAS No.: 6363-53-7
SDS CODE: E049

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 reliable data available.

1.3. Details of the supplier of the safety data sheet
SPI Pharma Inc.
Rockwood Office Park
503 Carr Road
Wilmington, Delaware 19809
(302) 360-7200

1.4. Emergency telephone number
Emergency number: (800) 424-9300 (CHEMTREC)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
GHS-US classification
Not classified

2.2. Label elements
GHS-US labelling
No labelling applicable

2.3. Other hazards
No additional information available

2.4. Unknown acute toxicity (GHS US)
No data available

SECTION 3: Composition/information on ingredients

Name: ADVANTOSE™ 100 Crystalline Maltose NF (Monohydrate)

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maltose monohydrate</td>
<td>(CAS No) 6363-53-7</td>
<td>100</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures
First-aid measures after inhalation: If respiratory irritation occurs upon inhalation, remove to fresh air. Seek medical attention if symptoms develop or persist.
First-aid measures after skin contact: Wash with water and soap. If skin irritation persists, seek medical attention.
First-aid measures after eye contact: Immediately rinse with plenty of water. If eye irritation persists, take medical advice.
First-aid measures after ingestion: If a large quantity has been ingested: Immediately get medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/injuries: Severe exposure to this product may produce some discomfort and gastrointestinal disturbances but symptoms are reversible and usually disappear when exposure stops.
Symptoms/injuries after inhalation: Overexposure may be irritating to the respiratory system.
Symptoms/injuries after skin contact: Not expected to be an irritant. Repeated or prolonged skin contact may cause irritation.
Symptoms/injuries after eye contact: Dust from this product may cause eye irritation. Significant irritation would not be expected.
### ADVANTOSE™ 100 Crystalline Maltose NF (Monohydrate)

**Safety Data Sheet**

according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

---

<table>
<thead>
<tr>
<th>Symptoms/injuries after ingestion</th>
<th>Ingestion of small amounts would not be expected to produce toxicity.</th>
</tr>
</thead>
</table>

#### 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: Powder, alcohol-resistant foam, water spray, carbon dioxide.

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

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Explosion hazard</td>
<td>Accumulation of airborne dusts may present an explosion hazard in the presence of an ignition source.</td>
</tr>
<tr>
<td>Reactivity</td>
<td>Stable under normal conditions of use.</td>
</tr>
</tbody>
</table>

#### 5.3. Advice for firefighters

Protective equipment for firefighters: Extra personal protection: complete protective clothing including self-contained breathing apparatus.

---

### SECTION 6: Accidental release measures

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

<table>
<thead>
<tr>
<th>For non-emergency personnel</th>
<th>Refer to section 8.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For emergency responders</td>
<td>Refer to section 8. Wear suitable protective clothing.</td>
</tr>
</tbody>
</table>

#### 6.2. Environmental precautions

Avoid discharge to the environment. Do not discharge into drains or the environment. Do not discharge into surface water.

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

For containment: Contains the discharged material.

Methods for cleaning up: Avoid raising powdered materials into airborne dust. Ventilate affected area. If sweeping of a contaminated area is necessary, use a dust suppressant agent. Sweep or shovel spills into appropriate container for disposal.

#### 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 contact with eyes. avoid breathing dust. Avoid raising powdered materials into airborne dust.

Hygiene measures: Wash hands thoroughly after handling. Handle in accordance with good industrial hygiene and safety practices.

#### 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)

Excipient.

---

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

**Exposure Guidelines**

General Product Information: Exposures should be minimized in accordance with good industrial hygiene practices.

Component Exposure Limits: ACGIH, OSHA, NIOSH or the provinces of Canada have not developed exposure limits for any of this product’s components.

Engineering Controls: Ventilation should be sufficient to effectively remove and prevent buildup of airborne dusts.

#### 8.2. Exposure controls

<table>
<thead>
<tr>
<th>Appropriate engineering controls</th>
<th>Provide local exhaust or general room ventilation to minimize exposure to dust.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal protective equipment</td>
<td>Safety glasses. Gloves. Protective clothing.</td>
</tr>
</tbody>
</table>
## Hand protection
Wear impervious gloves for prolonged contact.

## Eye protection
Safety glasses with side-shields.

## Skin and body protection
Wear suitable protective clothing. Wear long sleeves.

## Respiratory protection
In case of insufficient ventilation, wear suitable respiratory equipment.

### SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Powder</td>
</tr>
<tr>
<td>Colour</td>
<td>Whitish</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4.0-5.5 (30% water solution)</td>
</tr>
<tr>
<td>Melting point</td>
<td>164 - 169 °C</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 149 °C</td>
</tr>
<tr>
<td>Self ignition temperature</td>
<td>460 °C</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>290 - 295 °C</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Water: Soluble</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

#### 9.2. Other information
No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity
Stable under normal conditions of use.

#### 10.2. Chemical stability
Stable under normal conditions of use.

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

#### 10.4. Conditions to avoid
Avoid raising powdered materials into airborne dust.

#### 10.5. Incompatible materials
No additional information available

#### 10.6. Hazardous decomposition products
Carbon dioxide (CO2). Carbon monoxide. Low molecular weight hydrocarbons.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Maltose (69-79-4)</td>
<td></td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>&gt; 34800 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified</td>
</tr>
</tbody>
</table>
ADVANTOSE™ 100 Crystalline Maltose NF (Monohydrate)
Safety Data Sheet
according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

Germ cell mutagenicity : Not classified
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
Symptoms/injuries after inhalation : Overexposure may be irritating to the respiratory system.
Symptoms/injuries after skin contact : Not expected to be an irritant. Repeated or prolonged skin contact may cause irritation.
Symptoms/injuries after eye contact : Dust from this product may cause eyes irritation. Significant irritation would not be expected.
Symptoms/injuries after ingestion : Ingestion of small amounts would not be expected to produce toxicity.

SECTION 12: Ecological information

Toxicity
Persistence and degradability
No additional information available
Bioaccumulative potential
Mobility in soil
No additional information available
Other adverse effects
No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste disposal recommendations : Comply with applicable local, national and international regulation.
Additional information : Empty containers should be taken for recycle, recovery or waste in accordance with local regulation. Do not distribute, make available, furnish or reuse empty container. Puncture or otherwise destroy empty container before disposal. except for storage and shipment of original product.

SECTION 14: Transport information

In accordance with ADR / RID / ADNR / IMDG / ICAO / IATA
14.1. UN number
Not applicable
14.2. UN proper shipping name
Not applicable
14.3. Additional information
Other information : No supplementary information available.

Overland transport
No additional information available
Transport by sea
No additional information available
Air transport
No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations
No additional information available
15.2. International regulations
CANADA
No additional information available
EU-Regulations
No additional information available
Classification according to Regulation (EC) No. 1272/2008 [CLP]
No additional information available
ADVANTOSE™ 100 Crystalline Maltose NF (Monohydrate)
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Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]
No additional information available

15.2.2. National regulations
No additional information available

15.3. US State regulations
No supplementary information available

SECTION 16: Other information

<table>
<thead>
<tr>
<th>Abbreviations and acronyms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATE</td>
<td>acute toxicity estimate.</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service.</td>
</tr>
<tr>
<td>HCS</td>
<td>Hazard Communication Standard.</td>
</tr>
<tr>
<td>HMIS</td>
<td>Hazardous Materials Identification System.</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonised System.</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration.</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheet.</td>
</tr>
</tbody>
</table>

Date of SDS preparation : 05/01/2015
Other information : None.

NFPA health hazard : 0 - Exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials.
NFPA fire hazard : 0 - Must be preheated before ignition can occur.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

HMIS III Rating

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>0 Minimal Hazard - No significant risk to health</td>
</tr>
<tr>
<td>Flammability</td>
<td>0 Minimal Hazard</td>
</tr>
<tr>
<td>Physical</td>
<td>0 Minimal Hazard</td>
</tr>
<tr>
<td>Personal Protection</td>
<td>Safety glasses with side shields</td>
</tr>
</tbody>
</table>

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.