Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.
Dear Customer,

Thank you for your interest in Spectrum’s quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry’s most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com
SO219, Sorbitol, Powder, NF

Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Manufacturing Process Flowchart
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Allergen Statement
- Product Certificate of Analysis Sample(s)
- General Label Information – Sample Label
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance

1.June.2017
**Specification for Sorbitol, Powder, NF (SO219)**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>SO219</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Sorbitol, Powder, NF</td>
</tr>
<tr>
<td>CAS Number</td>
<td>50-70-4</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C(<em>6)H(</em>{14})O(_6)</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>182.17</td>
</tr>
<tr>
<td>MDL Number</td>
<td></td>
</tr>
<tr>
<td>Synonyms</td>
<td>D-Glucitol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSAY (D-Sorbitol; Anhydrous Basis)</strong></td>
<td>Min</td>
</tr>
<tr>
<td>pH OF A 10% SOLUTION</td>
<td>3.5</td>
</tr>
<tr>
<td>NICKEL (Ni)</td>
<td>1 ppm</td>
</tr>
<tr>
<td>WATER</td>
<td>1.5 %</td>
</tr>
<tr>
<td>RESIDUE ON IGNITION</td>
<td>0.1 %</td>
</tr>
<tr>
<td>REDUCING SUGARS</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>MICROBIAL LIMITS:</td>
<td></td>
</tr>
<tr>
<td>TOTAL PLATE COUNT</td>
<td>1,000 cfu/g</td>
</tr>
<tr>
<td>YEAST AND MOLD</td>
<td>100 cfu/g</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>RETEST DATE</td>
<td></td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
</tr>
<tr>
<td>APPEARANCE</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
</tr>
</tbody>
</table>

---

*Spectrum Chemical Mfg Corp*

**Corporate Headquarters:**
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

**West Coast Facility:**
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000
SAFETY DATA SHEET

Product code: SO219
Product Name: SORBITOL, POWDER, NF

Other means of identification
Synonyms:
(-)-Sorbitol
D-(-)-Sorbitol
D-1,2,3,4,5,6-Hexanohexol
D-Glucitol
D-Sorbite
D-Sorbitol
D-Sorbo
Esasorb
Glucarine
Glucitol
Gulitol
Karion
L-Gulitol
Multitol
Neosorb
Nivitin
Sionit
Sionit K
Sionite
Sionon
Siosan
Sorbicolan
Sorblande
Sorbite
Sorbo
Sorbo
Sorbostyl
Sorvilande
1,2,3,4,5,6-Hexanohexol
Glucitol, D-
Resulax
Sorbilax

CAS #: 50-70-4
RTECS #: LZ4290000
CI#: Not available

Recommended use of the chemical and restrictions on use
Recommended use: Used as an excipient in pharmaceutical formulations; Food products; Diluent in tablet formulations; In capsule formulation it is used as a plasticizer; In liquid preparations sorbitol is used as a vehicle in sugar-free formulations and as a stabilizer for drug, vitamin, and antacid suspensions; a suitable carrier to enhance the in vitro dissolution rate of indometacin; In syrups it prevents crystallization around the cap of bottles; Sorbitol is used in injectable and topical preparations; Sorbitol is used analytically as a marker for assessing liver blood flow. Cosmetics.

Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA  90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)
Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

| Combustible dust |

Label elements

Warning
May form combustible dust concentrations in air

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Keep away from all ignition sources including heat, sparks, and flame
Keep container closed and grounded
Prevent dust accumulations to minimize explosion hazard

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
<th>Trade Secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>50-70-4</td>
<td>100</td>
<td>*</td>
</tr>
</tbody>
</table>

Product code: SO219  Product name: SORBITOL, POWDER, NF
4. FIRST AID MEASURES

First aid measures
General Advice:  Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126).

Skin Contact:  Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.  Get medical attention if irritation develops.  Consult a physician if necessary.

Eye Contact:  Flush eye with water for 15 minutes.  Get medical attention if irritation occurs.  If symptoms persist, call a physician.

Inhalation:  Move to fresh air.  If not breathing, give artificial respiration.  If breathing is difficult, give oxygen.  Get medical attention.

Ingestion:  Do not induce vomiting without medical advice.  Never give anything by mouth to an unconscious person.  Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed
Symptoms  May cause skin irritation.  May cause eye irritation.  May cause irritation of respiratory tract.  May cause hypermotility, diarrhea.

Indication of any immediate medical attention and special treatment needed
Notes to Physician:  Treat symptomatically

Protection of first-aiders
First-Aid Providers:  Avoid exposure to blood or body fluids.  Wear gloves and other necessary protective clothing.  Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media
Suitable Extinguishing Media:  Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media:  No information available.

Specific hazards arising from the chemical
Hazardous Combustion Products:  Carbon oxides

Specific hazards:  May be combustible at high temperatures
Avoid generating dust
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard

Special Protective Actions for Firefighters
Specific Methods:  No information available.

Special Protective Equipment for Firefighters:  As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Avoid dispersal of dust in the air. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Nonsparking tools should be used.

Environmental precautions Prevent further leakage or spillage if safe to do so.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading. Prevent dust cloud.

Methods for cleaning up Use appropriate tools to put the spilled solid in a suitable waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions: Provide sufficient air exchange and/or exhaust in work rooms. Minimize dust generation and accumulation. Avoid dust formation. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. All equipment used when handling the product must be grounded. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Keep away from incompatible materials.

Safe Handling Advice: Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe vapours/dust. Do not ingest. Do not smoke. Keep away from heat and sources of ignition. Use only explosion-proof equipment. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions: Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials: Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol 50-70-4</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Canada

<table>
<thead>
<tr>
<th>Components</th>
<th>Alberta</th>
<th>British Columbia</th>
<th>Ontario</th>
<th>Quebec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol 50-70-4</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Product code: SO219  
Product name: SORBITOL, POWDER, NF
### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment) It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

- **Eye protection:** Goggles. Safety glasses with side-shields.
- **Skin and body protection:** Chemical resistant apron. Long sleeved clothing. Gloves.
- **Respiratory protection:** Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent.
- **Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

---

**Product code:** SO219  
**Product name:** SORBITOL, POWDER, NF
### 9. 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>Odor:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Formula:</td>
<td>C6H14O6</td>
</tr>
<tr>
<td>Appearance:</td>
<td>Powder</td>
</tr>
<tr>
<td>Taste:</td>
<td>Sweet</td>
</tr>
<tr>
<td>Color:</td>
<td>White</td>
</tr>
<tr>
<td>Molecular/Formula weight:</td>
<td>182.17</td>
</tr>
<tr>
<td>Flashpoint (°C/°F):</td>
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<tr>
<td>Flash Point Tested according to:</td>
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<td>Upper Explosion Limit (%):</td>
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<td>Melting point/range(°C/°F):</td>
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<td>Bulk density:</td>
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<td>Density (g/cm3):</td>
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<tr>
<td>VOC content (g/L):</td>
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</tr>
<tr>
<td>Viscosity:</td>
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<td>Appearance:</td>
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<td>Flash point (°C):</td>
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<tr>
<td>Autoignition Temperature (°C/°F):</td>
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<td>Boiling point/range(°C/°F):</td>
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<td>Specific gravity:</td>
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<td>Evaporation rate:</td>
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<tr>
<td>Odor threshold (ppm):</td>
<td>No information available</td>
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<tr>
<td>Miscibility:</td>
<td>No information available</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Very soluble in Acetone</td>
</tr>
<tr>
<td></td>
<td>Easily soluble in cold water</td>
</tr>
<tr>
<td></td>
<td>Easily soluble in hot water</td>
</tr>
<tr>
<td></td>
<td>Soluble in Methanol</td>
</tr>
<tr>
<td></td>
<td>Soluble in Isopropanol</td>
</tr>
<tr>
<td></td>
<td>Soluble in Butanol</td>
</tr>
<tr>
<td></td>
<td>Soluble in Cyclohexanol</td>
</tr>
<tr>
<td></td>
<td>Soluble in Phenol</td>
</tr>
<tr>
<td></td>
<td>Soluble in Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Soluble in Dimethylformamide</td>
</tr>
<tr>
<td></td>
<td>Soluble in pyridine</td>
</tr>
<tr>
<td></td>
<td>Soluble in acetamide solution</td>
</tr>
<tr>
<td></td>
<td>Soluble in cold alcohol</td>
</tr>
<tr>
<td></td>
<td>Soluble in hot alcohol</td>
</tr>
<tr>
<td></td>
<td>Practically insoluble in most organic solvents</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

**Reactivity**

Reactive with oxidizing agents

**Chemical stability**

Stability: Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:**

Hazardous polymerization does not occur

**Conditions to avoid:**


**Incompatible Materials:**

Oxidizing agents.

**Product code:** SO219

**Product name:** SORBITOL, POWDER, NF
Hazardous decomposition products: Carbon oxides.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion.

Acute Toxicity

Component Information

*Sorbitol - 50-70-4*

LD50/oral/rat = 15900 mg/kg Oral LD50 Rat
LD50/oral/mouse = 17800 mg/kg
LD50/dermal/rat = No information available
LD50/dermal/rabbit = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 15900 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 17800 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Product code: SO219

Product name: SORBITOL, POWDER, NF
Eye Contact: May cause eye irritation.

Inhalation Dust is irritating to respiratory tract.
Ingestion May cause gastrointestinal tract irritation with nausea, vomiting, hypermotility and diarrhea.

Aspiration hazard No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity No information available
Sensitization: No information available
Mutagenic Effects: May affect genetic material
Carcinogenic effects: Not considered carcinogenic

<table>
<thead>
<tr>
<th>Components</th>
<th>ACGIH - Carcinogens</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
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</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

Reproductive toxicity No data is available
Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity
STOT - single exposure No information available
STOT - repeated exposure No information available
Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity
Ecotoxicity effects: No data available.

Persistence and degradability: No information available
Bioaccumulative potential: No information available
Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Product code: SO219 Product name: SORBITOL, POWDER, NF
13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: None
ERG No: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available

TDG (Canada)
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available

ADR
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

IMO / IMDG
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available
IMDG Page: No information available
Marine Pollutant: No information available
MFAG: No information available
Maximum Quantity: No information available

RID

Product code: SO219
Product name: SORBITOL, POWDER, NF
**14. TRANSPORT INFORMATION**

- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Classification Code:** No information available
- **Description:** No information available

**ICAO**

- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Description:** No information available

**IATA**

- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Risk:** No information available
- **Packing Group:** No information available
- **Description:** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>Present</td>
<td>Present KE-31708</td>
<td>Present</td>
<td>Present (8)-50</td>
<td>Present</td>
<td>Present</td>
<td>Present 200-061-5</td>
</tr>
</tbody>
</table>

**U.S. Regulations**

- **Sorbitol**
  - FDA - 21 CFR - Total Food Additives: 100.130 101.80 101.9 175.300 175.320 176.210 177.1390 177.2420 182.90 184.1835

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

- **Chemicals Known to the State of California to Cause Cancer:**
  - This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

- **Chemicals Known to the State of California to Cause Reproductive Toxicity:**
  - This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Components</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
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</thead>
<tbody>
<tr>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

**CERCLA/SARA**

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Product code:** SO219  **Product name:** SORBITOL, POWDER, NF
### U.S. TSCA

<table>
<thead>
<tr>
<th>Components</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

### Canada

**WHMIS hazard class:**
Non-controlled

**Canada Controlled Products Regulation:**
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

### Inventory

<table>
<thead>
<tr>
<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I - Toxic Substances</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

### EU Classification

**R-phrase(s)**
not determined (not applicable)

**S -phrase(s)**
one

<table>
<thead>
<tr>
<th>Components</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbitol</td>
<td></td>
<td>No information</td>
<td></td>
</tr>
</tbody>
</table>

The product is classified in accordance with Annex VI to Directive 67/548/EEC

**Indication of danger:**
None.

---

**Product code:** SO219  **Product name:** SORBITOL, POWDER, NF

---
16. OTHER INFORMATION

Preparation Date: 06/03/2015
Revision Date: 06/03/2015
Prepared by: Sonia Owen

Disclaimer:
All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet
Manufacturer

Product Covered: SO219, Sorbitol, Powder, NF

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com

1 June 2017
Manufacturing Process Flowchart

Sorbitol, Powder, NF - SO219

1. Fresh cassava (tapioca starch)
2. Mixing in water and pH adjustment
3. Enzymatic hydrolysis
4. Filtration
5. Demineralization
6. Evaporation
7. Hydrogenation
8. Filtration
9. Packaging
Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Inc

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA
Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum’s two manufacturing facilitates by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01
Initial Certification Date: 27 December 1994
Certificate Issue Date: 29 January 2016
Certificate Expiry Date: 14 September 2018

Calin Moldovean, President
Intertek Testing Services NA, Inc.
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.
This is to certify that the quality management system of

**Spectrum China Ltd.**

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of **ISO 9001: 2008**

The quality management system is applicable to:

*Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.*

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018

**Authorised Signature:** Calin Moldovean – President, Business Assurance

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website [http://www.cnca.gov.cn](http://www.cnca.gov.cn) of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.
January 03, 2017

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certifies that our USP, NF, FCC, EP, BP, JP, and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follow:

Spectrum Gardena, California: 2020632
Spectrum New Brunswick, New Jersey: 2246824

Thank you for your interest with Spectrum products. Please feel free to contact me at 310-516-8000, extension 5610 or via email at mdang@spectrumchemical.com if I may be of further assistance.

Sincerely,

Michael Dang
Manager, GMP Compliance
July 18, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO219</td>
<td>Sorbitol, Powder, NF</td>
</tr>
</tbody>
</table>

Spectrum is an FDA registered and inspected drug establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum-Shanghai, China: 3006174778

Thank you for your interest with Spectrum products. Please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

[Signature]

Oralia Chavez
Quality Assurance Specialist
May 23, 2016

Re: Sorbitol, Powder, NF- SO219

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical Sorbitol, Powder, NF- SO219 is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
May 23, 2016

Re: Sorbitol, Powder, NF- SO219

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Sesame Seed).

Sorbitol, Powder, NF- SO219

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
**Certificate Of Analysis**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>SO219</th>
<th>Lot Number</th>
<th>2GC0502</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Sorbitol, Powder, NF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>50-70-4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C(<em>6)H(</em>{14})O(_6)</td>
<td>Molecular Weight</td>
<td>182.17</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASSAY (D-Sorbitol; Anhydrous Basis)</strong></td>
<td>min</td>
<td>max</td>
</tr>
<tr>
<td><strong>pH OF A 10% SOLUTION</strong></td>
<td>3.5</td>
<td>7.0</td>
</tr>
<tr>
<td><strong>NICKEL (Ni)</strong></td>
<td>1 ppm</td>
<td>&lt;1 ppm</td>
</tr>
<tr>
<td><strong>WATER</strong></td>
<td>1.5 %</td>
<td>0.3 %</td>
</tr>
<tr>
<td><strong>RESIDUE ON IGNITION</strong></td>
<td>0.1 %</td>
<td>&lt;0.1 %</td>
</tr>
<tr>
<td><strong>REDUCING SUGARS</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>MICROBIAL LIMITS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL PLATE COUNT</strong></td>
<td>1,000 cfu/g</td>
<td>&lt;1,000 cfu/g</td>
</tr>
<tr>
<td><strong>YEAST AND MOLD</strong></td>
<td>100 cfu/g</td>
<td>&lt;100 cfu/g</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>RETEST DATE</strong></td>
<td>31-DEC-2018</td>
<td></td>
</tr>
<tr>
<td><strong>DATE OF MANUFACTURE</strong></td>
<td>01-DEC-2016</td>
<td></td>
</tr>
<tr>
<td><strong>APPEARANCE</strong></td>
<td>WHITE POWDER</td>
<td></td>
</tr>
<tr>
<td><strong>RESIDUAL SOLVENTS</strong></td>
<td>TO PASS TEST</td>
<td>NO RESIDUAL SOLVENTS USED</td>
</tr>
</tbody>
</table>

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ

Certificate Of Analysis Results Certified by:  
Ibad Tirmizi  
Director of Quality  
Spectrum Chemical Mfg. Corp.

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum’s chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.
Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

**WARNING**
- May form combustible (explosive) dust-air mixtures.
- Keep away from all ignition sources including heat, sparks and flame • Keep container closed and grounded • Prevent dust accumulations to minimize explosion hazard.
- This material has been evaluated per GHS criteria and is not classified as hazardous under GHS. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.
- KEEP FROM CHILDREN

**Sorbitol**
(D-Glucitol)

CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data Sheet (SDS) prior to use.

**MAXIMUM LIMITS**
- Microbial limits To pass test
- Nickel 1 µg/g
- Water 1.5%
- Residue on Ignition 0.1%
- Reducing Sugars To pass test
- Residual Solvents To pass test

WARNING: This product contains a chemical known to the State of California to cause cancer.

**GHS Hazard Pictograms**
- YELLOW: Oxidizer
- RED: Flammable
- GREEN: General Storage
- BLUE: Health Hazard
- WHITE: Corrosive

**Chemical Emergency:** (800)424-9300
www.SpectrumChemical.com
January 26, 2016

**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products’ Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of six characters, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum’s Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

*Example:* ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of seven characters. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

*Example:* 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michael Dang
Manager, GMP Compliance
Stability – Shelf Life Guidance

Product Covered: SO219, Sorbitol, Powder, NF

Spectrum Chemical’s manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, SO219, Sorbitol, Powder, NF, is assigned a 24 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605