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,

Michael Dang
Director, Quality Systems & GMP Compliance
mdang@spectrumchemical.com

24. September 2019
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- Safety Data Sheet (SDS)
- Manufacturing Process Flowchart
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
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- Product Allergen Statement
- Product Aflatoxin Statement
- Product Certificate of Analysis Sample(s)
- General Label Information – Sample Label
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance
<table>
<thead>
<tr>
<th>Item Number</th>
<th>MA165</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Mannitol, Powder, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>69-65-8</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C₆H₁₄O₆</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>182.17</td>
</tr>
<tr>
<td>MDL Number</td>
<td>Synonyms: Cordycepic Acid ; 1,2,3,4,5,6-Hexahexol ; Mannite ; D-Mannitol</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
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</thead>
<tbody>
<tr>
<td><strong>ASSAY (DRIED BASIS)</strong></td>
<td>Min: 97.0  Max: 102.0 %</td>
</tr>
<tr>
<td><strong>MELTING RANGE</strong></td>
<td>165° -170°C</td>
</tr>
<tr>
<td><strong>APPEARANCE OF SOLUTION</strong></td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td><strong>LOSS ON DRYING</strong></td>
<td>0.5 %</td>
</tr>
<tr>
<td><strong>NICKEL</strong></td>
<td>1 μg/g</td>
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<tr>
<td><strong>CONDUCTIVITY @ 25 C</strong></td>
<td>20 μS/cm</td>
</tr>
<tr>
<td><strong>RELATED SUBSTANCES</strong></td>
<td>TO PASS TEST</td>
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<tr>
<td><strong>REDUCING SUGARS</strong></td>
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<td><strong>MICROBIAL LIMITS:</strong></td>
<td></td>
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<tr>
<td><strong>TOTAL AEROBIC MICROBIAL COUNT</strong></td>
<td>10⁶ cfu/g</td>
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<tr>
<td><strong>TOTAL COMBINED MOLDS AND YEASTS COUNT</strong></td>
<td>10⁵ cfu/g</td>
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<tr>
<td><strong>ESCHERICHIA COLI</strong></td>
<td>Negative</td>
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<tr>
<td><strong>ELEMENTAL IMPURITIES</strong></td>
<td>AS REPORTED</td>
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<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
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<td><strong>EXPIRATION DATE</strong></td>
<td></td>
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<tr>
<td><strong>DATE OF MANUFACTURE</strong></td>
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<tr>
<td><strong>APPEARANCE</strong></td>
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<td><strong>RESIDUAL SOLVENTS</strong></td>
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SAFETY DATA SHEET

Preparation Date: 6/4/2014
Revision Date: 5/6/2019
Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: MA165
Product Name: MANNITOL, POWDER, USP

Other means of identification

Synonyms: Manna sugar
Mannite
D-Mannitol
1,2,3,4,5,6-Hexanehexol

CAS #: 69-65-8
RTECS #: OP2060000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: In Foods.
Uses advised against: No information available

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

Distributed by:
TekniScience
2425 Édouard Michelin Blvd.
Terrebonne, Qc Canada J6Y 4P2
Telephone: 1-800-267-9799

Order Online At: https://www.spectrumchemical.com
Emergency telephone number: Chemtrec 1-800-424-9300
Contact Person: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not 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)

Label elements

Not classified
3. COMPOSITION/INFORMATION ON INGREDIENTS

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<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

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

Eye Contact: Flush eyes 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 eye/skin irritation
Ingestion may cause nausea, vomiting, and diarrhea
Dehydration
Thirst
May cause central nervous system effects

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: Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Product code: MA165 Product name: MANNITOL, POWDER, USP
Hazardous combustion products: Carbon Monoxide, Carbon Dioxide.

Specific hazards: May be combustible at high temperatures.

**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: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental precautions: No information available.

**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.

Methods for cleaning up: Sweep up and shovel into suitable containers for disposal. 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. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

**Safe Handling Advice:**
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe dust. 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. Store at room temperature in the original container. Store away from incompatible materials.

**Incompatible Materials:**
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

National occupational exposure limits
**United States**

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WEEL</th>
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**Canada**

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<th>Canada - Ontario</th>
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**Australia and Mexico**

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<th>Mexico</th>
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<td>Mannitol</td>
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<td>None</td>
</tr>
</tbody>
</table>

**Appropriate engineering controls**

**Engineering measures to reduce exposure:**
Ensure adequate ventilation. 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.

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

**Personal Protective Equipment**

**Eye protection:** Safety glasses with side-shields. or Goggles

**Skin and body protection:**
- Long sleeved clothing
- Chemical resistant apron
- Gloves

**Respiratory protection:** Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:** Solid
**Appearance:** Fine crystalline powder.
**Color:** White.

**Odor:** Odorless.
**Taste:** Sweetish.

**Molecular/Formula weight (g/mole):** 182.17
**Flammability (solid, gas):** no data available

**Flashpoint (°C/°F):** No information available

**Product code:** MA165  **Product name:** MANNITOL, POWDER, USP
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


Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products:
Carbon monoxide. Carbon dioxide.

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:
Ingestion. Inhalation.

Product code: MA165 Product name: MANNITOL, POWDER, USP Page 5 / 11
**Acute Toxicity**

**Component Information**

<table>
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<th>Component</th>
<th>CAS No</th>
<th>LD50/oral/rat</th>
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<th>LD50/dermal/rabbit</th>
<th>LD50/dermal/rat</th>
<th>LC50/inhalation/rat</th>
<th>LC50/inhalation/mouse</th>
<th>Other LD50 or LC50 information</th>
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<td>13500 mg/kg</td>
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**Product Information**

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</thead>
<tbody>
<tr>
<td>LD50/oral/mouse</td>
<td>Value - Acute Tox = 22000 mg/kg</td>
</tr>
</tbody>
</table>

LD50/dermal/rabbit

Value - Acute Toxicity = No information available

LD50/dermal/rat

VALUE - Acute Toxicity = 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.

**Eye Contact:**

May cause eye irritation.

**Inhalation**

May cause irritation of respiratory tract.

**Ingestion**

Low hazard. Ingestion of large quantities can cause nausea, vomiting, hypermotility, diarrhea, dehydration, excessive thirst, diuresis (increased formation of urine/increased urination). It may also affect behavior/central nervous system (somnolence, dizziness, agitation, disorientation, convulsions, lethargy, confusion, headache), cardiovascular system (sensation of constriction or pain in the chest, increase in intravascular volume resulting in congestive heart failure, blood pressure elevation), urinary system (changes in tubules - including acute renal failure, acute tubular necrosis).

**Aspiration hazard**

No information available.

**Product code:** MA165

**Product name:** MANNITOL, POWDER, USP

Page 6 / 11
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>
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<tr>
<th>Component</th>
<th>CAS No.</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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<td>Not listed</td>
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</tr>
</tbody>
</table>

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

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 in soil: No information available.

Other adverse effects: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Product code: MA165

Product name: MANNITOL, POWDER, USP
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>
<th></th>
</tr>
</thead>
<tbody>
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<td>None</td>
<td>None</td>
<td>None</td>
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</table>

### 14. TRANSPORT INFORMATION

**DOT**
- **UN-No:** Not Regulated
- **Proper Shipping Name:** No information available
- **Hazard Class:** No information available
- **Subsidiary Class:** No information available
- **Packing group:** No information available
- **Emergency Response Guide Number:** No information available
- **Marine Pollutant:** No data available
- **DOT RQ (lbs):** No information available
- **Special Provisions:** No Information available
- **Symbol(s):** No information available
- **Description:** 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
- **Marine Pollutant:** No Information available
- **Description:** No information available

**ADR**
- **UN Number:** Not regulated
- **Proper Shipping Name:** No information available
- **Transport hazard class(es):** No information available
- **Packing group:** No information available
- **Subsidiary Risk:** No information available

**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
- **Marine Pollutant:** No information available

**RID**
- **UN Number:** Not Regulated
- **Proper Shipping Name:** No information available
- **Transport hazard class(es):** No information available
- **Subsidiary Risk:** No information available
- **Packing group:** No information available

**ICAO (air)**

**Product code:** MA165  **Product name:** MANNITOL, POWDER, USP
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

IATA
UN Number: Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es): No information available
Subsidiary Risk: No information available
Packing group: No information available
Precautionary Statements - Response: No information available
Special Provisions: No information available

15. REGULATORY INFORMATION

International Inventories

<table>
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<tr>
<th>Component</th>
<th>CAS No</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>China IECSC</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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<tbody>
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<td>Present KE-23061</td>
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<td>Present (8)-49,(9)-1375</td>
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<td>Present 200-711-8</td>
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U.S. Regulations

Mannitol
FDA - 21 CFR - Total Food Additives 100.130, 101.80, 101.9, 175.300, 175.320, 177.1390, 177.2420, 180.25
- List Sourced from EAFUS


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>Component</th>
<th>CAS No</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
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CERCLA/SARA

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<tr>
<th>Component</th>
<th>CAS No</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>
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<tr>
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U.S. TSCA

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<th>Component</th>
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<th>TSCA 8(d) - Health and Safety Reporting</th>
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<tbody>
<tr>
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</tr>
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</table>
Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Component
Mannitol 69-65-8 (100)

Combustible Dust - Category 1: May form combustible dust concentrations in air (factors such as combustibility and explosiveness of dusts including composition and shape and size of particles could cause substance to belong to ‘Combustible dust’ hazard class)

Canada Hazardous Products Regulation

This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

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EU Classification

EU GHS - SV - CLP 1272/2008

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EU - CLP (1272/2008)

R-phrase(s)

none

S-phrase(s)

none

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<th>Safety Phrases</th>
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</table>

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

Indication of danger:
Not dangerous

16. OTHER INFORMATION

Preparation Date: 6/4/2014

Product code: MA165 Product name: MANNITOL, POWDER, USP Page 10 / 11
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
Manufacturing Process Flowchart

Mannitol, Powder, USP - MA165

- Dextrose → Dissolution → Chemical isomerization
- Concentration → Second separation → Decoloration & ion exchange
- Hydrogenation → Decoloration & ion exchange → Concentration
- Decoloration & filtration → Centrifugal dewatering → Crystallization
- Crystallization → Centrifugal dewatering
- Warehousing
- Packing

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
CERTIFICATE
OF REGISTRATION

This is to certify that the management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street,
Gardena, California, 90248, United States

Additional Site: 13915 South Main Street,
Los Angeles, California, 90061, United States

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

Certificate Number:
94-316m

Initial Certification Date:
27 December 1994

Date of Certification Decision:
22 January 2019

Issuing Date:
22 January 2019

Valid Until:
28 January 2022

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.,
900 Chelmsford Street,
Lowell, MA 01851.
USA.
This appendix identifies the locations covered by the management system of:

**Spectrum Chemicals and Laboratory Products, Inc.**

This appendix is linked to the Main Certificate # 94-316m and cannot be shown nor reproduced without it.

**Spectrum Chemicals and Laboratory Products, Inc.**

769 Jersey Avenue,
New Brunswick, New Jersey, 08901, United States

755 Jersey Avenue,
New Brunswick, New Jersey, 08901, United States

777 Jersey Avenue,
New Brunswick, New Jersey, 08901, United States

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

**Spectrum Chemicals and Laboratory Products, Inc.**

7400 N. Oracle, Suite 201,
Tucson, Arizona, 85704, United States

The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, compounding pharmacy, cosmetic, fragrance, biotechnology, environmental and process industries.

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.
管理体系认证
注册证书

兹证明，以下组织：

斯百全化学（上海）
有限公司

注册地址：上海市松江区申港路3802号41幢
经营地址：上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售。

统一社会信用代码：
91310000777627048K

证书编号：
111310001

首次认证日期：
2015年11月17日

认证决定日期：
2018年10月15日

签发日期：
2018年10月15日

有效期至：
2021年11月10日

Calin Moldovean
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited
是 UKAS 认可的认证机构，
注册号为 014

对于此证书的签署，Intertek仅对获证组织承担认证协议所规定的义务，而不对其他组织承担任何义务。此证书的有效性基于获证组织能够根据Intertek的体系认证要求保持其体系得到维持。可通过电子邮件certificate.validation@intertek.com或通过手机扫描二维码对证书有效性进行确认。此证书的所有权归为Intertek。在必要时证书持有者应按要求归还证书。

获证组织必须定期接受监督审核并持续合格方可保持证书年度有效。证书信息可在国家认证监管官网http://www.cnca.gov.cn查询。
This is to certify that the management system of:

**Spectrum China Ltd.**

Registered Address: Building 41, No.3802, Shengang Road, Songjiang District, Shanghai, China
Business Address: Building A20, No.3802, Shengang Road, Songjiang District, Shanghai, China

has been registered by Intertek as conforming to the requirements of:

**ISO 9001:2015**

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals.

**Unified Social Credit Identifier:**
91310000777627048K

**Certificate Number:**
111310001

**Initial Certification Date:**
17 November 2015

**Date of Certification Decision:**
15 October 2018

**Issuing Date:**
15 October 2018

**Valid Until:**
10 November 2021

**Calin Moldovean**
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

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 organisation maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificates.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.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.
Certification of Compliance with current Good Manufacturing Practices

January 08, 2019

Dear Valued Customer:

Spectrum Chemical Mfg Corp 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 and parts 110 and 111 of the Code of Federal Regulations, respectively.

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

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

Thank you for your interest in 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
Director, Quality Systems & GMP Compliance
September 24, 2019

**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies 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>MA165</td>
<td>Mannitol, Powder, USP</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

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

Sincerely,

[Signature]

Oralia Chavez
Quality Assurance Specialist
June 20, 2016

Re: Mannitol, Powder, USP- MA165

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 Mannitol, Powder, USP- MA165

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
June 20, 2016

Re: Mannitol, Powder, USP- MA165

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; Tree nuts; Wheat; Peanuts; Cereals containing Gluten).

Mannitol, Powder, USP- MA165

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 6, 2016

Re: Mannitol, Powder, USP- MA165

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Mannitol, Powder, USP- MA165

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>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item Number</strong></td>
<td>MA165</td>
<td>Lot Number</td>
</tr>
<tr>
<td><strong>Item</strong></td>
<td>Mannitol, Powder, USP</td>
<td></td>
</tr>
<tr>
<td><strong>CAS Number</strong></td>
<td>69-65-8</td>
<td>Molecular Weight</td>
</tr>
<tr>
<td><strong>Molecular Formula</strong></td>
<td>( \text{C}<em>6\text{H}</em>{14}\text{O}_6 )</td>
<td></td>
</tr>
<tr>
<td><strong>Test</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ASSAY (DRIED BASIS)</strong></td>
<td>97.0%</td>
<td>102.0%</td>
</tr>
<tr>
<td><strong>MELTING RANGE</strong></td>
<td>165°C - 170°C</td>
<td>166°C - 167°C</td>
</tr>
<tr>
<td><strong>APPEARANCE OF SOLUTION</strong></td>
<td>TO PASS TEST</td>
<td>PASS TEST</td>
</tr>
<tr>
<td><strong>LOSS ON DRYING</strong></td>
<td>0.5%</td>
<td>0.16%</td>
</tr>
<tr>
<td><strong>NICKEL</strong></td>
<td>1 ( \mu \text{g/g} )</td>
<td>0.0075 ( \mu \text{g/g} )</td>
</tr>
<tr>
<td><strong>CONDUCTIVITY @ 25°C</strong></td>
<td>20 ( \mu \text{S/cm} )</td>
<td>1.44 ( \mu \text{S/cm} )</td>
</tr>
<tr>
<td><strong>RELATED SUBSTANCES</strong></td>
<td>TO PASS TEST</td>
<td>PASS TEST</td>
</tr>
<tr>
<td><strong>REDUCING SUGARS</strong></td>
<td>TO PASS TEST</td>
<td>PASS TEST</td>
</tr>
<tr>
<td><strong>MICROBIAL LIMITS:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL AEROBIC MICROBIAL COUNT</strong></td>
<td>( 10^3 \text{ cfu/g} )</td>
<td>(&lt; 10^3 \text{ cfu/g} )</td>
</tr>
<tr>
<td><strong>TOTAL COMBINED MOLDS AND YEASTS COUNT</strong></td>
<td>( 10^2 \text{ cfu/g} )</td>
<td>(&lt; 10^2 \text{ cfu/g} )</td>
</tr>
<tr>
<td><strong>ESCHERICHIA COLI</strong></td>
<td>Negative</td>
<td>NEGATIVE</td>
</tr>
<tr>
<td><strong>ELEMENTAL IMPURITIES</strong></td>
<td>AS REPORTED</td>
<td>COMPLIES WITH STANDARD</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
<td>PASS TEST</td>
</tr>
<tr>
<td><strong>EXPIRATION DATE</strong></td>
<td>17-JAN-2021</td>
<td></td>
</tr>
<tr>
<td><strong>DATE OF MANUFACTURE</strong></td>
<td>18-JAN-2019</td>
<td></td>
</tr>
<tr>
<td><strong>APPEARANCE</strong></td>
<td>WHITE</td>
<td>CRYSTALLINE POWDER</td>
</tr>
<tr>
<td><strong>RESIDUAL SOLVENTS</strong></td>
<td>TO PASS TEST</td>
<td>NO RESIDUAL SOLVENTS USED</td>
</tr>
</tbody>
</table>

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

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.
The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.
**Mannitol**

**CAS 69-65-8**

(1,2,3,4,5,6-Hexanohexol; Mannite; D-Mannitol)

**Powder, U.S.P.**

**MA165 2.5 KG**

**Use Care:**

This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. 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.

**Caution:**

For manufacturing, processing or repacking. Not intended for use in injectable dosage forms. Read and understand the label and Safety Data Sheet (SDS) prior to use.

**Keep From Children**

**Assay (Dried Basis):** 97.0-102.0%

**Melting Range:** 165°-170°C

**Appearance of Solution:** To pass test

**Maximun Limits**

- **Loss on Drying:** 0.5%
- **Nickel:** ≤ 1 µg/g
- **Conductivity @ 25°C:** 20 µS/cm
- **Related Substances:** To pass test
- **Reducing Sugars:** To pass test
- **Total Aerobic Microbial Count:** ≤ 1,000 cfu/g
- **Total Combined Molds and Yeasts Count:** ≤ 100 cfu/g
- **Residual Solvents:** To pass test

**Empirical Formula, Formula Weight and Technical Specifications Panel**

- **C6H14O6**
- **F.W. 182.17**

**Warning, Safety Data and Precautionary Information**

- **Chemical Emergency: (800)424-9300**
- **www.SpectrumChemical.com**

**Storage Color Band**

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.
February 1, 2019

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
4 = Pharmacy, NJ 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,

Howard Lau,
Quality Assurance Specialist
Stability – Shelf Life Guidance

Product Covered: MA165, Mannitol, Powder, USP

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

The product, MA165, Mannitol, Powder, USP, 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