spectrum®

Scientific Documentation

S9700, Sucrose, NF, EP, BP, bioCERTIFIED [™], Endotoxin Tested

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp

769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300

Ver4.06 03.November.2021

S9700, Sucrose, NF, EP, BP, bioCERTIFIED [™], Endotoxin Tested

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| Item Number | <u>\$9700</u> |
|-------------------|---|
| Item | Sucrose, NF, EP, BP, bioCERTIFIED (TM), Endotoxin Tested |
| CAS Number | 57-50-1 |
| Molecular Formula | $C_{12}H_{22}O_{11}$ |
| Molecular Weight | 342.30 |
| MDL Number | |
| Synonyms | Cane Sugar ; Beta-D-Fructofuranosyl-alpha-D-glucopyranoside |

| Test | Specifi | ication |
|--------------------------------------|--|-----------|
| | Min | Max |
| APPEARANCE | White, colorless powder to fine crystals | |
| APPEARANCE OF SOLUTION | TO PASS TEST | |
| SPECIFIC ROTATION @ 20°C | +66.3 to+67.09° | |
| LOSS ON DRYING | | 0.1 % |
| SULFITE (as SO ₂) | | 10 ppm |
| CONDUCTIVITY | | 35 S/cm |
| COLOR VALUE | | 75 |
| REDUCING SUGARS | TO PASS TEST | |
| DEXTRINS | TO PASS TEST | |
| ELEMENTAL IMPURITIES | AS REPORTED | |
| MICROBIAL LIMITS: | | |
| BACTERIAL ENDOTOXINS | | 0.6 EU/g |
| TOTAL AEROBIC MICROBIAL COUNT | | 100 cfu/g |
| TOTAL YEAST AND MOLD COUNT | | 100 cfu/g |
| BILE TOLERANT GRAM-NEGATIVE BACTERIA | None detected | |
| ESCHERICHIA COLI | None detected | |
| SALMONELLA | None detected | |
| CANDIDAS ALBICANS | None detected | |
| STAPHYLOCOCCUS AUREUS | None detected | |
| PSEUDOMONAS AERUGINOSA | None detected | |
| RESIDUAL SOLVENTS | AS REPORTED | |
| IDENTIFICATION | TO PASS TEST | |
| RETEST DATE | | |

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

Revision date 01-June-2021

Hazard statements

Crystals

May form combustible dust concentrations in air

Appearance Crystalline powder or

| 1. Identification | | |
|---|---|--|
| Product identifier | | |
| Product Name | SUCROSE, NF, EP, BP, BIOCERTIFIED(TM), ENDOTOXIN TESTED | |
| Other means of identification | | |
| Product Code(s) | S9700 | |
| Synonyms | None | |
| Recommended use of the chemica | al and restrictions on use | |
| Recommended use | No information available | |
| Restrictions on use | No information available | |
| Details of the supplier of the safety | y data sheet | |
| <u>Supplier Address</u> Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000 | | |
| Emergency telephone number | | |
| Emergency Telephone | Chemtrec 1-800-424-9300 | |
| | | |
| 2. Hazard(s) identification | | |
| <u>Classification</u> | | |
| Combustible dust | Yes | |
| Hazards not otherwise classified (Not applicable | HNOC) | |
| Label elements Warning | | |

Revision Number 1

Physical state Solid

Odor No information available

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

Other information No information available.

3. Composition/information on ingredients

Substance

| Chemical name | CAS No | Weight-% | Trade secret |
|---------------|---------|----------|--------------|
| Sucrose | 57-50-1 | 100 | * |

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

| Inhalation | Remove to fresh air. |
|---|--|
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. |
| Skin contact | Wash skin with soap and water. |
| Ingestion | Clean mouth with water and drink afterwards plenty of water. |
| Most important symptoms and effects, both acute and delayed | |
| Symptoms | No information available. |

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

fire-fighters

| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the | |
|--|--|--|
| Large Fire | surrounding environment. CAUTION: Use of water spray when fighting fire may be inefficient. | |
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. | |
| Specific hazards arising from the chemical | Avoid generation of dust. Fine dust dispersed in air may ignite. | |
| Explosion data Sensitivity to mechanical impact none. | | |
| Sensitivity to static discharge | yes. | |
| Special protective equipment for | Firefighters should wear self-contained breathing apparatus and full firefighting turnout | |

gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

| Personal precautions | Ensure adequate ventilation. Avoid generation of dust. Avoid contact with eyes. Use personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharges. | |
|--|---|--|
| Other information | Refer to protective measures listed in Sections 7 and 8. | |
| Methods and material for containment and cleaning up | | |
| Methods for containment | Prevent further leakage or spillage if safe to do so. Prevent dust cloud. | |
| Methods for cleaning up | Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. Pick up and transfer to properly labeled containers. | |

| 7. Handling and storage | | |
|--|--|--|
| Precautions for safe handling | | |
| Advice on safe handling | Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures against static discharges. | |
| Conditions for safe storage, including any incompatibilities | | |
| Storage Conditions | Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children. | |

8. Exposure controls/personal protection

Control parameters

Exposure Limits

| Chemical name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|---------------|-------------------|-------------------------|------------|
| Sucrose | No data available | 15 mg/m³ TWA | - |
| 57-50-1 | | 5 mg/m ³ TWA | |

Appropriate engineering controls

| Engineering controls | Showers |
|----------------------|----------------------|
| | Eyewash stations |
| | Ventilation systems. |

Individual protection measures, such as personal protective equipment

.

| Eye/face protection | Wear safety glasses with side shields (or goggles). |
|--------------------------|---|
| Skin and body protection | No special protective equipment required. |

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Do not breathe dust.

9. Physical and chemical properties

Information on basic physical and chemical properties **Physical state** Solid Crystalline powder or Crystals Appearance Color White Odor No information available **Odor threshold** No information available Property Values Remarks • Method рΗ no data available None known 185 - 186 °C / 365 - 366.8 °F Melting point / freezing point None known Boiling point / boiling range no data available None known Flash point no data available None known Evaporation rate no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known Upper flammability or explosive No data available limits Lower flammability or explosive No data available limits Vapor pressure No data available None known Vapor density no data available None known **Relative density** 1.587 None known Soluble in water None known Water solubility Solubility(ies) Slightly soluble in Ethanol None known Insoluble in Ether Moderately soluble in alvcerol Moderately soluble in pyridine **Partition coefficient** -3.70 None known Autoignition temperature no data available None known **Decomposition temperature** None known **Kinematic viscosity** no data available None known Dynamic viscosity No data available None known Other information No information available **Explosive properties Oxidizing properties** No information available Softening point No information available Molecular weight 342.30 VOC Content (%) No information available Liquid Density No information available No information available **Bulk density**

10. Stability and reactivity

| Reactivity | No information available. |
|------------------------------------|---|
| Chemical stability | Stable under normal conditions. |
| Possibility of hazardous reactions | None under normal processing. |
| Conditions to avoid | Excessive heat. Heating in air. dust formation. |
| Incompatible materials | None known based on information supplied. |
| Hazardous decomposition products | None known based on information supplied. |

11. Toxicological information

Information on likely routes of exposure

Product Information

| Inhalation | Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract. | |
|--|--|--|
| Eye contact | Specific test data for the substance or mixture is not available. | |
| Skin contact | Specific test data for the substance or mixture is not available. | |
| Ingestion | Specific test data for the substance or mixture is not available. | |
| Symptoms related to the physical, chemical and toxicological characteristics | | |

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|-------------------|-------------|-----------------|
| Sucrose | 29700 mg/kg (Rat) | - | - |
| 57-50-1 | | | |

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

| Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity | No information available. No information available. No information available. No information available. |
|---|--|
| Reproductive toxicity | No information available. |
| STOT - single exposure STOT - repeated exposure Target organ effects | No information available. No information available. respiratory system, Eyes. |
| Aspiration hazard | No information available. |
| Other adverse effects | No information available. |
| Interactive effects | No information available. |

12. Ecological information

| Ecotoxicity | The environmental impact of this product has not been fully investigated. |
|--|---|
| Persistence and degradability Bioaccumulation | No information available. Inherently biodegradable. |
| Other adverse effects | No information available. |

Waste treatment methods

| Waste from residues/unused products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
|--|---|
| Contaminated packaging | Do not reuse empty containers. |

14. Transport information

| DOT | not regulated |
|------------|---------------|
| TDG | not regulated |
| <u>MEX</u> | not regulated |
| ICAO (air) | not regulated |
| IATA | not regulated |
| IMDG | not regulated |
| RID | not regulated |
| ADR | not regulated |
| ADN | not regulated |

15. Regulatory information

International Inventories

TSCA

Complies

| DSL/NDSL | Complies |
|---------------|--|
| EINECS/ELINCS | Complies |
| ENCS | This product complies with ENCS: |
| IECSC | This product complies with China: |
| KECL | Complies |
| PICCS | Complies |
| AICS | All the constituents of this material are listed on the Australian Inventory of Chemical |
| | Substances (AICS). |

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

<u>NFPA</u>

Health hazards0Flammability1Instability0Physical and chemical properties-HMIS1Health hazards0Flammability0Physical hazards0Personal protectionX

Key or legend to abbreviations and acronyms used in the safety data sheet

| Legend Section | 18: EXPOSURE CONTROLS/ | PERSONAL PROTE | CTION | |
|----------------|---------------------------|----------------|-------|----------------------------------|
| TWA | TWA (time-weighted averag | ge) ST | ΓEL | STEL (Short Term Exposure Limit) |
| Ceiling | Maximum limit value | | | |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date01-June-2021Revision NoteNo information available.Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

spectrum

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.

| Catalog Number | Product Name |
|----------------|--|
| S9700 | Sucrose, NF, EP, BP, bioCERTIFIED [™] |
| | Endotoxin Tested |

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: | <u>2020632</u> |
|-----------------------------|----------------|
| 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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clony

Oralia Chavez Quality Assurance Specialist

Spectrum[®] **S9700**, Sucrose, NF, EP, BP, bioCERTIFIED ™, Endotoxin Tested

Source Statement

The above mentioned catalog item is manufactured from plant origin material (sugarcane). No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.



Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 24 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

• Aflatoxins

• Pesticides

• Antibiotics



RE: Elemental Impurities - Sucrose, NF, EP, BP, bioCERTIFIED ™, Endotoxin Tested (Cat# S9700)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843



RE: Residual Solvents - Sucrose, NF, EP, BP, bioCERTIFIED ™, Endotoxin Tested (Cat# S9700)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

| Residual Solvent | Class | Expected Concentration |
|------------------|-------|------------------------|
| 2-Propanol | 3 | < 5000 ppm |

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <u>TechServices@spectrumchemical.com.</u>

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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WEST COAST FACILITY

14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

spectrum®

RED: Flammable

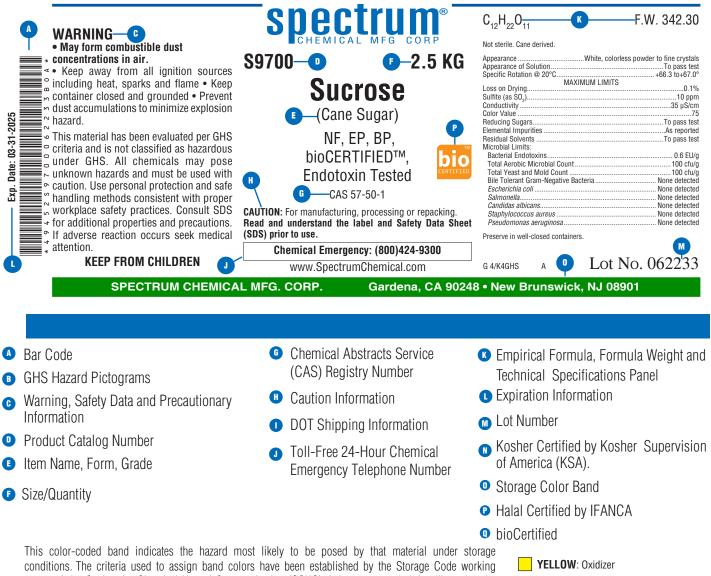
GREEN: General Storage

BLUE: Health Hazard

WHITE: Corrosive

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.



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.

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

spectrum

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 <u>guality_assurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Oulu Clony

Oralia Chavez, Quality Assurance Specialist

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A N IS O 9 001 : 201 5 R E GI STE R ED C O M P AN Y