

# **Scientific Documentation**

# Fructose, Granular, USP

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.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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### **Specification for Fructose, Granular, USP (FR106)**

Item Number	FR106
Item	Fructose, Granular, USP
CAS Number	57-48-7
Molecular Formula	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>
Molecular Weight	180.16
MDL Number	
Synonyms	D-Fructose ; Levulose ; Fruit Sugar

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
COLOR OF SOLUTION	NO MORE COLOR THAN STANDARD	
ACIDITY		0.50 ml
LOSS ON DRYING		0.5 %
RESIDUE AFTER IGNITION		0.5 %
CHLORIDE (Cl)		0.018 %
SULFATE		0.025 %
ARSENIC (As)		1 ug/g
CALCIUM AND MAGNESIUM (AS Ca)		0.005 %
ELEMENTAL IMPURITIES	AS REPORTED	
HYDROXYMETHYLFURFURAL	NO CHERRY-RED COLOR DEVELOPS	
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

#### Spectrum Chemical Mfg Corp

#### Spectrum Chemical Mfg Corp

 Corporate Headquarters:
 West Coast Facility:

 New Brunswick, NJ 08901
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# **Certificate Of Analysis**

Item Number	FR106	Lot Number	1MC0738
Item	Fructose, Granular, USP	CAS Number	57-48-7
Molecular Formula	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	Molecular Weight	180.16

тгст	SPECIF	ICATION	DECULT
TEST	MIN	MAX	RESULT
ASSAY (DRIED BASIS)	98.0	102.0 %	101.8 %
COLOR OF SOLUTION	NO MORE COLOR THAN STANDARD		NO MORE COLOR THAN STANDARD
ACIDITY		0.50 ml	<0.20 ml
LOSS ON DRYING		0.5 %	0.1 %
RESIDUE AFTER IGNITION		0.5 %	0.0 %
CHLORIDE (CI)		0.018 %	<0.018 %
SULFATE		0.025 %	<0.025 %
ARSENIC (As)		1 ug/g	<0.05 μg/g
CALCIUM AND MAGNESIUM (AS Ca)		0.005 %	<0.005 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
HYDROXYMETHYLFURFURAL	NO CHERRY- RED COLOR DEVELOPS		NO CHERRY-RED COLOR DEVELOPS
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
RETEST DATE			15-MAR-2024
DATE OF MANUFACTURE			04-FEB-2020
APPEARANCE			WHITE GRANULES
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 2022
REANALYZED ON			16-MAR-2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 14-APR-23 08:12:30

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



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.

Certificate of Analysis Results Approved By:

JRUIZ Jesus Ruiz 17-APR-23 16:55:13

# SAFETY DATA SHEET

Revision date 14-November-2022

1. Identification		
Product identifier		
Product Name	FRUCTOSE, GRANULAR, USP	
Other means of identification		
Product Code(s)	FR106	
Synonyms	None	
Recommended use of the chemical	and restrictions on use	
Recommended use	No information available	
Restrictions on use	No information available	
Details of the supplier of the safety	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 (HNOC) Not applicable		

Label elements Warning		
Hazard statements May form combustible dust concentrations in air		
Appearance granules Crystals	Physical state Solid	Odor No information available



Revision Number 2

Other information No information available.

#### 3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Fructose	57-48-7	100

#### 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

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	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.	
Hazardous combustion products Carbon Monoxide, Carbon Dioxide.		
Explosion data Sensitivity to mechanical impact none.		
Sensitivity to static discharge	yes.	
Special protective equipment for fire-fighters	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.	

-	11		
	Handlind	and storage	
		and Storade	

#### 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 LimitsThe following ingredients are the only ingredients of the product above the cut-off level (or<br/>level that contributes to the hazard classification of the mixture) which have an exposure<br/>limit applicable in the region for which this safety data sheet is intended or other<br/>recommended limit. At this time, the other relevant constituents have no known exposure<br/>limits from the sources listed here.Appropriate engineering controlsShowers<br/>Eyewash stations<br/>Ventilation systems.Individual protection measures, such as personal protective equipmentWear 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		
Appearance	granules Crystals		
Color	White		
Odor	No information available		
Odor threshold	No information available		
oddi threshold			
Property_	Values	Remarks • Method	
pH	no data available	None known	
Melting point / freezing point	> 100 °C / 212 °F	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	1.6	None known	
Water solubility	Soluble in water	None known	
Solubility(ies)	Soluble in Alcohol	None known	
	Soluble in Acetone		
Partition coefficient	No data available	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			
Explosive properties	No information available		
Oxidizing properties	No information available		
Softening point	No information available		
Molecular weight	No information available		
VOC Content (%)	No information available		
Liquid Density	No information available		
Bulk density	No information available		
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#### 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 No information available

#### 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 Aspiration hazard	No information available. No information available. 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 No information available. Inherently biodegradable.

Other adverse effects No information available.

#### 13. Disposal considerations

#### 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
MEX	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
RECL PICCS AICS	Complies Complies 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

#### <u>SARA 313</u>

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

NFPA Health hazards 0 Flammability 1 Instability 0 Physical and chemical properties -HMIS Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X Key or legend to abbreviations and acronyms used in the safety data sheet Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit) Ceilina 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, Fundicide, 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 date**

14-November-2022

No information available.

Revision Note 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	
FR106	Fructose, Granular, USP	

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: Spectrum-New Brunswick, NJ: 2020632 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>qualityassurance@spectrumchemical.com</u>

Sincerely,

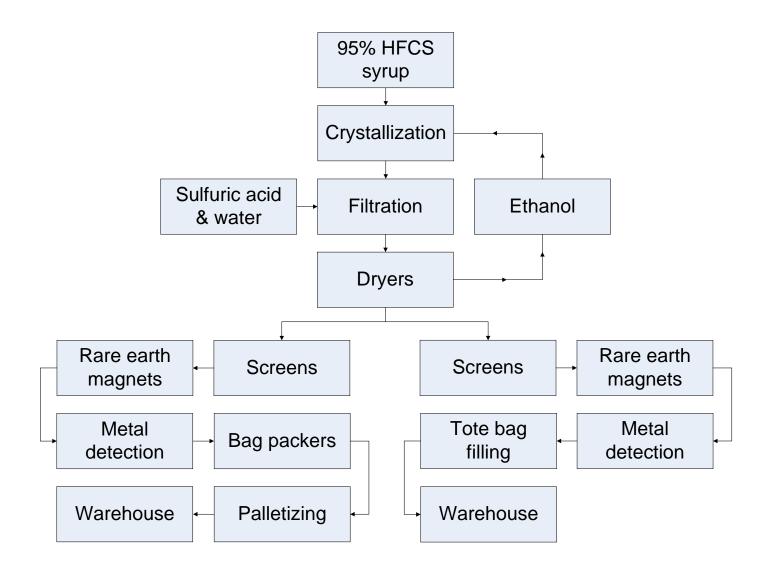
Oulu Umy

Oralia Chavez Quality Assurance Specialist



### **Manufacturing Process Flowchart**

### Fructose, Granular, USP - FR106



#### 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

### FR106, Fructose, Granular, USP

#### **Source Statement**

The above mentioned catalog item is manufactured by plant derived material (corn). 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

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

#### **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

#### **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.

#### **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 18 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

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#### RE: Elemental Impurities - Fructose, Granular, USP (Cat# FR106)

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

AN ISO 9001:2015 REGISTERED COMPANY

# spectrum

#### RE: Residual Solvents - Fructose, Granular, USP (Cat# FR106)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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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www.spectrumchemical.com

# spectrum®

#### **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. Below you will find a typical label example for this catalog item.

	WARNING		$C_{6}H_{12}O_{6}$	F.W. 180.16
est Date: 00-00	<ul> <li>WARNING</li> <li>May form combustible dust concentrations in air.</li> <li>Keep away from all ignition sources including heat, sparks and flame • Keep container closed and grounded • Prevent dust accumulations to minimize explosion hazard.</li> <li>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.</li> </ul>	FR106SIZ SYEnceCD-Fructose; Fruit Sugar; Levulose)GranularUSPCAS 57-48-7CAUTION: For manufacturing, processing orRead and understand the label and Safety DataSheet (SDS) prior to use.Chemical Emergency: (800)424-9300www.SpectrumChemical.com	Assay (Dried Basis) MAZ Color of Solution Acidity Residue After Igniti Chloride Sulfate Calcium and Magne Elemental Impuritie Hydroxymethylfurfu Residual Solvents	98.0-102.0% XIMUM LIMITS 

#### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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