

Scientific Documentation

Chondroitin Sulfate Sodium Salt, USP Dietary Supplement

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 Chondroitin Sulfate Sodium Salt, USP Dietary Supplement (C1610)

Item Number	C1610
Item	Chondroitin Sulfate Sodium Salt, USP Dietary Supplement
CAS Number	9082-07-9
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Sodium Chondroitin Sulfate

Test	Specification	
	Min	Max
CHONDROITIN SULFATE SODIUM (DRIED BASIS)	90.0 %	105.0 %
SPECIFIC ROTATION, [a] _D 25	-20.0° to -30.0°	
RESIDUE ON IGNITION	20.0 %	30.0 %
pH (1 IN 100)	5.5	7.5
CLARITY AND COLOR OF SOLUTION	TO PASS TEST	
LOSS ON DRYING		12.0 %
NONSPECIFIC DISSACCHARIDES		10 %
PROTEIN		6.0 %
CHLORIDE		0.50 %
SULFATE		0.24 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
MERCURY (Hg)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
ELECTROPHORETIC PURITY	TO PASS TEST	
MICROBIAL LIMITS:		
TOTAL BACTERIAL COUNT		10 ³ cfu/g

Test	Specification	
	Min	Max
TOTAL YEASTS AND MOLDS COUNT		10 ² cfu/g
SALMONELLA	NEGATIVE	
ESCHERICHIA COLI	NEGATIVE	
EXPIRATION DATE		
MANUFACTURE DATE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



Certificate Of Analysis

Item Number	C1610	Lot Number	2NC0143
Item	Chondroitin Sulfate Sodium Salt, USP Dietary Supplement	CAS Number	9082-07-9

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
CHONDROITIN SULFATE SODIUM (DRIED BASIS)	90.0 %	105.0 %	92.2 %	
SPECIFIC ROTATION, [a] _D 25	-20.0° to -30.0°		-21.6°	
RESIDUE ON IGNITION	20.0 %	30.0 %	22.2 %	
pH (1 IN 100)	5.5	7.5	6.6	
CLARITY AND COLOR OF SOLUTION	TO PASS TEST		PASSES TEST	
LOSS ON DRYING		12.0 %	9.0 %	
NONSPECIFIC DISSACCHARIDES		10 %	<10 %	
PROTEIN		6.0 %	3.8 %	
CHLORIDE		0.50 %	<0.5 %	
SULFATE		0.24 %	<0.24 %	
ELEMENTAL IMPURITIES:				
CADMIUM (Cd)	AS REPORTED		<1 ppm	
LEAD (Pb)	AS REPORTED		<1 ppm	
ARSENIC (As)	AS REPORTED		<2 ppm	
MERCURY (Hg)	AS REPORTED		<1 ppm	
ELECTROPHORETIC PURITY	TO PASS TEST		PASSES TEST	
MICROBIAL LIMITS:				
TOTAL BACTERIAL COUNT		10³ cfu/g	<10 CFU/G	
TOTAL YEASTS AND MOLDS COUNT		10² cfu/g	<10 CFU/G	
SALMONELLA	NEGATIVE		NEGATIVE	
ESCHERICHIA COLI	NEGATIVE		NEGATIVE	
EXPIRATION DATE			22-FEB-2026	
MANUFACTURE DATE			23-FEB-2024	
APPEARANCE			CREAM COLOR FINE POWDER	
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST	
CLASS 3 (solvent) / ETHANOL			<5000 ppm	

TECT	SPECIFICATION		DECLUT
TEST	MIN	MAX	RESULT
IDENTIFICATION			PASSES TEST

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 25-MAR-24 05:50:27

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 25-MAR-24 08:42:59

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.





Revision date 22-August-2022

Revision Number 3

1. Identification

Product identifier

Product Name Chondroitin Sulfate Sodium Salt, USP

Other means of identification

Product Code(s) C1610

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

Supplier Address

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

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Physical state Solid Odor No information available

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Chondroitin Sulfate Sodium Salt	9082-07-9	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

5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Hazardous combustion products Carbon dioxide (CO2). Hydrocarbons. Sulfur oxides. Produce toxic and/or corrosive

substances on contact with water.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none

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.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up 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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protectionNo special protective equipment required.

Respiratory protection 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 Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

No information available **Appearance** No information available Color Odor No information available **Odor threshold** No information available

Remarks • Method Property Values

рΗ Almost neutral None known Melting point / freezing point > 200 °C / 392 °F None known Boiling point / boiling range no data available None known Flash point no data available None known no data available **Evaporation rate** 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 None known Relative density 1.9 Soluble in water None known Water solubility None known

Very slightly soluble in acetone Solubility(ies) Very slightly soluble in alcohol

Very slightly soluble in Ether

Partition coefficient **Autoignition temperature Decomposition temperature**

Kinematic viscosity no data available Dynamic viscosity

No data available

No data available

no data available

None known None known

None known None known None known

Other information

No information available **Explosive properties Oxidizing properties** No information available No information available Softening point Molecular weight No information available **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 None known based on information supplied.

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

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Specific test data for the substance or mixture is not available. Skin contact

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
Chondroitin Sulfate Sodium Salt	> 10 g/kg (Rat)	-	-
9082-07-9			

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

Skin corrosion/irritation No information available. 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

STOT - single exposure STOT - repeated exposure **Aspiration hazard**

No information available. No information available. No information available.

No information available.

Interactive effects

Other adverse effects

No information available.

12. Ecological information

The environmental impact of this product has not been fully investigated. **Ecotoxicity**

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable.

No information available. Other adverse effects

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

<u>IMDG</u> not regulated

RID not regulated

ADR not regulated

ADN not regulated

15. Regulatory information

International Inventories

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed

on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise

exempted from inventory listing requirements

DSL/NDSL Complies

EINECS/ELINCS Does not Comply
ENCS This product complies with ENCS:

IECSC This product complies with China:

KECL Does not Comply **PICCS** Does not Comply

AICS This product does not comply with 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).

CFRCI A

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 0 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)

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 date 22-August-2022 Revision Note 22-August-2022 No 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



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
C1610	Chondroitin Sulfate Sodium Salt, USP Dietary Supplement

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,

Oralia Chavez

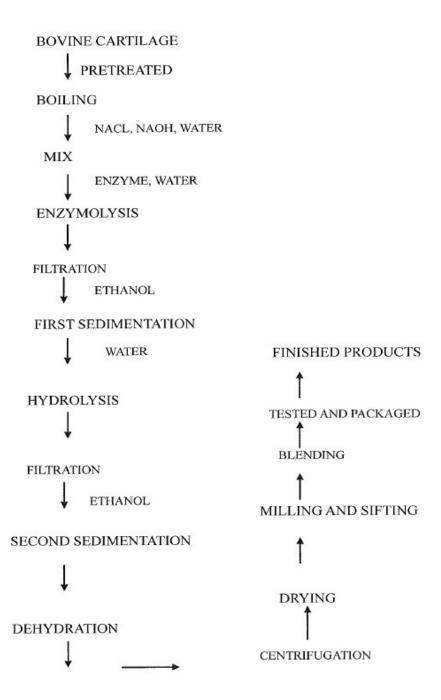
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Chondroitin Sulfate Sodium Salt, USP Dietary Supplement (Cat# C1610)



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



C1610, Chondroitin Sulfate Sodium Salt, USP Dietary Supplement

Source Statement

The above mentioned catalog item is manufactured from animal origin (Bovine: Bos taurus). No plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using BSE/TSE materials nor any ruminant material from BSE/TSE countries. The viral inactivation process for the bovine raw material includes sedimentation with high concentration of ethanol. The processing step for microbial minimization of the bovine raw material includes boiling with high temperature, and sedimentation with high concentration of ethanol.

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

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 this material 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 36 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



RE: Elemental Impurities – Chondroitin Sulfate Sodium Salt, USP Dietary Supplement (Cat# C1610)

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 TechServices@spectrumchemical.com.

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 – Chondroitin Sulfate Sodium Salt, USP Dietary Supplement (Cat# C1610)

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
Ethanol	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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
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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.

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.

KEEP FROM CHILDREN

C1610 SIZ SY Chondroitin Sulfate Sodium Salt

(Sodium Chondroitin Sulfate)

USP Dietary Supplement
CAS 9082-07-9

CAUTION: For manufacturing, processing or repacking. Do not feed to cattle or other ruminants. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

The sodium salt of the sulfated linear glycosaminoglycan obtained from bovine cartilages of healthy and domestic animals used for food by humans.

Chondroitin Sulfate Sodium (Dried Basis)	90.0-105.0%
Specific Rotation, [\alpha]_0^{25}	
Residue on Ignition	
pH (1 in 100)	
Clarity and Color of Solution	
Loss on DryingMAXIMUM LIMITS	12.0%
Nonspecific Dissaccharides	10%
Protein	6.0%
Chloride	
Sulfate	
Elemental Impurities	
Electrophoretic Purity	
Residual Solvents	
Microbial Limits:	
Total Bacterial Count	103 cfu/a
Total Yeasts and Molds Count	
Salmonella	
Escherichia coli	

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 2/15GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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