



# Scientific Documentation

## S1093, Silver Sulfadiazine, Micronized, USP

Not appropriate for regulatory submission.  
Please visit [www.spectrumchemical.com](http://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

Ver4.03 19.September.2017



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,

A handwritten signature in black ink, appearing to read "Alan Wang", is positioned above the typed name.

Alan Wang, MSQA, ASQ CQA  
Director of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

**S1093**, Silver Sulfadiazine, Micronized, USP

## Table of Contents

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

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CHEMICAL MFG CORP



## Specification for Silver Sulfadiazine, Micronized, USP (S1093)

Item Number	S1093
Item	Silver Sulfadiazine, Micronized, USP
CAS Number	22199-08-2
Molecular Formula	C <sub>10</sub> H <sub>9</sub> AgN <sub>4</sub> O <sub>2</sub> S
Molecular Weight	357.14
MDL Number	
Synonyms	Sulfadiazine Silver

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0%
PARTICLE SIZE	TO PASS TEST	
SILVER CONTENT	29.3	30.5%
LOSS ON DRYING		0.5%
NITRATE		0.1%
ORGANIC IMPURITIES		TO PASS TEST
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

### **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

Preparation Date: 09/28/2016

Revision Date: Not Applicable

Revision Number: Not Applicable

### 1. IDENTIFICATION

#### Product identifier

**Product code:** S1093  
**Product Name:** SILVER SULFADIAZINE, MICRONIZED, USP

#### Other means of identification

**Synonyms:** No information available  
**CAS #:** 22199-08-2  
**RTECS #** WP1950000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** For manufacturing, processing, repacking, or for prescription compounding.  
**Uses advised against** Not for food or drug use.

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

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

#### Label elements

##### **Warning**

##### **Hazard statements**

Causes skin irritation  
 Causes serious eye irritation  
 May cause respiratory irritation



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Use only outdoors or in a well-ventilated area  
Wear protective gloves  
Wear eye/face protection

**Precautionary Statements - Response**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.  
IF ON SKIN: Wash with plenty of water  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash it before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

**Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed  
Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Silver Sulfadiazine	22199-08-2	100

**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 skin irritation persists, call a physician.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention.

**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. Obtain medical attention.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** Causes skin irritation. Causes serious eye irritation. Irritating to respiratory system.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

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

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray, mist, or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Oxides. Nitrogen Oxides. Sulfur Oxides.

**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:** Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid breathing dust. Avoid dust formation. Ensure adequate ventilation. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage. Prevent product from entering drains. Prevent entry into waterways, sewers.

**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**

**Product code:** S1093

**Product name:** SILVER  
SULFADIAZINE, MICRONIZED, USP

**Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Ensure adequate ventilation. Avoid dust formation. Keep away from incompatible materials.

**Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe dust. Do not ingest. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities****Technical Measures/Storage Conditions:**

Protect from light. Sensitive to light. Store in light-resistant containers. Moisture sensitive. 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  
Mineral acids  
Sodium Hypochlorite  
Acrolein  
calcium hypochlorite  
Maleic anhydride  
Nitrosyl perchlorate  
Tri-iso-butyl aluminum

<b>8. EXPOSURE CONTROLS/PERSONAL PROTECTION</b>
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**Control parameters****National occupational exposure limits****United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Silver Sulfadiazine	22199-08-2	None	None	None	None

**Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Silver Sulfadiazine	22199-08-2	None	None	None	None

**Australia and Mexico**

Components	CAS-No.	Australia	Mexico
Silver Sulfadiazine	22199-08-2	None	None

**Appropriate engineering controls****Engineering measures to reduce exposure:**

Ensure adequate ventilation, especially in confined areas. 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

<b>Eye protection:</b>	Goggles or Safety glasses with side-shields
<b>Skin and body protection:</b>	Gloves. Chemical resistant apron. Long sleeved clothing.
<b>Respiratory protection:</b>	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. Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient.
<b>Hygiene measures:</b>	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

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White.
<b>Odor:</b> Slight.	<b>Taste</b> No information available.	<b>Formula:</b> C10H9AgN4O2S
<b>Molecular/Formula weight:</b> 357.14	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 285°C (545°F) - dec.	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Slightly soluble in Acetone Practically insoluble in alcohol Practically insoluble in Chloroform Practically insoluble in Ether	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with strong oxidizing agents

**Chemical stability**

**Stability:** Sensitive to light. Moisture Sensitive. Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Exposure to moisture. Exposure to light. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents  
Mineral acids  
Sodium Hypochlorite  
Acrolein  
calcium hypochlorite  
Maleic anhydride  
Nitrosyl perchlorate  
Tri-iso-butyl aluminum

**Hazardous decomposition products:** Carbon oxides. Nitrogen oxides (NOx). Sulfur oxides. Silver oxides.

**Other Information**

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

**11. TOXICOLOGICAL INFORMATION**

**Information on likely routes of exposure**

**Principal Routes of Exposure:**  
Inhalation. Ingestion. Skin. Eyes.

**Acute Toxicity**

**Component Information**

Silver Sulfadiazine	
CAS-No.	22199-08-2

- LD50/oral/rat =** > 10 g/kg Oral LD50 Rat
- LD50/oral/mouse =** No information available
- LD50/dermal/rabbit =** No information available
- LD50/dermal/rat =** > 10 g/kg Oral LD50
- LC50/inhalation/rat =** No information available
- LC50/inhalation/mouse =** No information available
- Other LD50 or LC50 information =** No information available

**Product Information**

**LD50/oral/rat =**  
**VALUE- Acute Tox Oral =** No information available

**LD50/oral/mouse =**  
**Value - Acute Tox Oral =** No information available

**Product code:** S1093

**Product name:** SILVER  
SULFADIAZINE, MICRONIZED, USP

**LD50/dermal/rabbit**

VALUE-Acute Tox Dermal = No information available

**LD50/dermal/rat**

VALUE -Acute Tox Dermal = No information available

**LC50/inhalation/rat**

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

**LC50/Inhalation/mouse**

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

**Symptoms****Skin Contact:** Causes skin irritation.**Eye Contact:** Causes eye irritation.**Inhalation** Irritating to respiratory system. May cause allergy or asthma symptoms or breathing difficulties if inhaled.**Ingestion** Health injuries are not known or expected under normal use.**Aspiration hazard** No information available.**Delayed and immediate effects as well as chronic effects from short and long-term exposure****Chronic Toxicity** No information available.**Sensitization:** No information available.**Mutagenic Effects:** No information available**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Silver Sulfadiazine	22199-08-2	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*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****Product code:** S1093**Product name:** SILVER  
SULFADIAZINE, MICRONIZED, USP

STOT - single exposure            Respiratory system.  
 STOT - repeated exposure        No information available.  
 Target Organs:                      No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:**                No data available.

**Persistence and degradability:**    No information available

**Bioaccumulative potential:**        No information available.

**Mobility:**                              No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

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

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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Silver Sulfadiazine	22199-08-2	None	None	None	None

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

**IMO / IMDG**

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

**RID**

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

**ICAO**

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

**IATA**

UN-No: Not Regulated  
 Proper Shipping Name: No information available  
 Hazard Class: No information available  
 Subsidiary Risk: No information available  
 Packing Group: No information available  
 ERG Code: No information available  
 Special Provisions: No information available

<b>15. REGULATORY INFORMATION</b>
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**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Silver Sulfadiazine	22199-08-2	Not Listed	Not present	Not present	Not present	Not present	Present	Present 244-834-5

**U.S. Regulations****California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Product code:** S1093

**Product name:** SILVER  
 SULFADIAZINE, MICRONIZED, USP

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Silver Sulfadiazine	22199-08-2	Not Listed	Not Listed	Not Listed	Not Listed

#### CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Silver Sulfadiazine	22199-08-2	None	None	None	None	None

#### U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Silver Sulfadiazine	22199-08-2	Not Applicable	Not Applicable

#### Canada

#### WHMIS hazard class:

D2B Toxic materials

#### Canada Controlled Products Regulation:

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

#### Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Silver Sulfadiazine	22199-08-2	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Silver Sulfadiazine	22199-08-2	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Silver Sulfadiazine	22199-08-2	Not listed

#### EU Classification

#### R-phrase(s)

R36/37/38 - Irritating to eyes, respiratory system and skin.

#### S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37 - Wear suitable gloves.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Silver Sulfadiazine	22199-08-2		No information	

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

#### Indication of danger:

Xi - Irritant.

**Xi**



## 16. OTHER INFORMATION

**Preparation Date:** 09/28/2016  
**Revision Date:** Not Applicable  
**Prepared by:** Roumann Pangilinan

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

**End of Safety Data Sheet**



## **Manufacturer**

Product Covered: S1093, Silver Sulfadiazine, Micronized, USP

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

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

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

Sincerely,

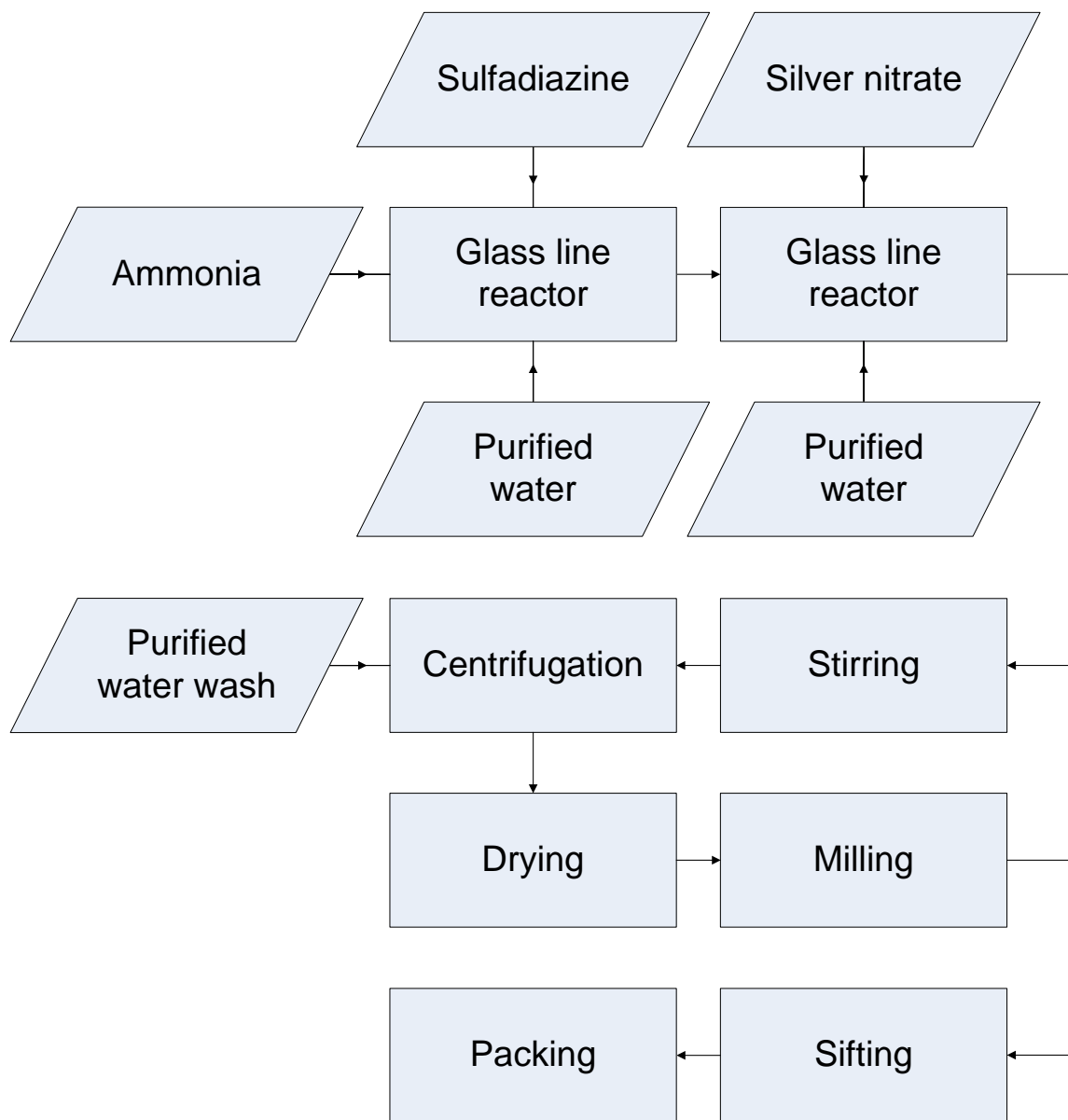
A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA  
Director of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)



## Manufacturing Process Flowchart

### Silver Sulfadiazine, Micronized, USP - S1093



#### ***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 quality management system of:

## Spectrum Chemicals and Laboratory Products, Inc.

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

Additional sites: 13915 South Main Street, Los Angeles, California,  
90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

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

## ISO 9001:2015

The quality management system is applicable to:

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

**Certificate Number:**

94-316m-03

**Initial Certification Date:**

27 December 1994

**Certificate Issue Date:**

31 July 2017

**Certificate Expiry Date:**

28 January 2019



A handwritten signature in black ink, appearing to read 'Calin Moldovean', written over a horizontal line.

**Authorized Signature**

**Calin Moldovean**

President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek  
900 Chelmsford Street, Lowell, MA, USA



# APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

## Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.



# Certificate of Registration

# Intertek

This is to certify that the quality management system of

## Spectrum China Ltd.

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

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

## ISO 9001: 2008

The quality management system is applicable to:

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

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



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

*Authorised Signature: 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 organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



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

July 13, 2017

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

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 of the Code of Federal Regulations.

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

Spectrum-Gardena, CA:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum-Shanghai, China:	<u>3006174778</u>

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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,



Oralia Chavez  
Quality Assurance Specialist

September 19, 2017

**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
S1093	Silver Sulfadiazine, Micronized, 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: 2020632  
Spectrum-New Brunswick, NJ: 2246824  
Spectrum-Shanghai, China: 3006174778

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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,



Oralia Chavez  
Quality Assurance Specialist



May 16, 2016

Re: Silver Sulfadiazine, Micronized, USP-S1093

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

Silver Sulfadiazine, Micronized, USP-S1093

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](mailto: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 17, 2016

Re: Silver Sulfadiazine, Micronized, USP- S1093

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 SO<sub>2</sub>; Tree nuts; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Silver Sulfadiazine, Micronized, USP- S1093

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto: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 17, 2016

Re: Silver Sulfadiazine, Micronized, USP- S1093

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.

Silver Sulfadiazine, Micronized, USP- S1093

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

Item Number	S1093	Lot Number	2GG0268
Item	Silver Sulfadiazine, Micronized, USP		
CAS Number	22199-08-2		
Molecular Formula	C <sub>10</sub> H <sub>9</sub> AgN <sub>4</sub> O <sub>2</sub> S	Molecular Weight	357.14

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0	102.0%	101.4 %
PARTICLE SIZE	TO PASS TEST		PASSES TEST
SILVER CONTENT	29.3	30.5%	29.8 %
LOSS ON DRYING		0.5%	0.3 %
NITRATE		0.1%	<0.1 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			31-DEC-2020
DATE OF MANUFACTURE			01-DEC-2015
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 1 (solvent) / BENZENE			<2 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ

Certificate Of Analysis Results Certified by



Ibad Tirmizi  
Director of Quality  
Spectrum Chemical Mfg. Corp.



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

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

## Label Information

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

**SPECTRUM**<sup>®</sup>

**S1093** **1 KG**

**Silver Sulfadiazine**

Micronized  
U.S.P.

CAS 22199-08-2

**WARNING**  
 • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.  
 • Wear protective gloves, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**  
[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

**KEEP FROM CHILDREN**

**Exp. Date: 03-31-2025**

**C<sub>10</sub>H<sub>9</sub>AgN<sub>4</sub>O<sub>2</sub>S** F.W. 357.14

Assay (Dried Basis)..... 98.0-102.0%  
 Particle Size .....To pass test  
 Chromatographic Purity.....To pass test  
 Silver Content ..... 29.3-30.5%

**MAXIMUM LIMITS**

Loss on Drying..... 0.5%  
 Nitrate ..... 0.1%  
 Residual Solvents .....To pass test

**LIGHT SENSITIVE, MOISTURE SENSITIVE:** Keep tightly closed in light-resistant containers.

**Lot No. 062233**

**SPECTRUM CHEMICAL MFG. CORP.** Gardena, CA 90248 • New Brunswick, NJ 08901

- |   |  |   |
|---|--|---|
| <b>A</b> Bar Code   | <b>F</b> Size/Quantity   | <b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel |
| <b>B</b> GHS Hazard Pictograms                              | <b>G</b> Chemical Abstracts Service (CAS) Registry Number      | <b>L</b> Expiration Information   |
| <b>C</b> Warning, Safety Data and Precautionary Information | <b>H</b> Caution Information                                   | <b>M</b> Lot Number   |
| <b>D</b> Product Catalog Number                             | <b>I</b> DOT Shipping Information                              | <b>N</b> Kosher Certified by Kosher Supervision of America (KSA).             |
| <b>E</b> Item Name, Form, Grade                             | <b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number |   |
| <b>O</b> 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.

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

### 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

January 26, 2016

**RE: Lot Numbering System**

Dear Valued Customer:

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

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

**Example:** ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

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

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

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

**Example:** 2AA0706 = The 706<sup>th</sup> 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](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,



Michael Dang  
Manager, GMP Compliance



## Stability – Shelf Life Guidance

Product Covered: S1093, Silver Sulfadiazine, Micronized, USP

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

The product, S1093, Silver Sulfadiazine, Micronized, USP, is assigned a 60 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

A handwritten signature in black ink that reads "Adan R. Hernandez".

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