Scientific Documentation

S1510, Colloidal Silicon Dioxide, NF, EP

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
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Ver4.06 03.November.2021

S1510, Colloidal Silicon Dioxide, NF, EP

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Specification for Colloidal Silicon Dioxide, NF, EP (S1510)

Item Number	S1510
Item	Colloidal Silicon Dioxide, NF, EP
CAS Number	7631-86-9
Molecular Formula	SiO_2
Molecular Weight	60.08
MDL Number	
Synonyms	Silica, colloidal anhydrous

Test	Specification	
	Min	Max
ASSAY (IGNITED BASIS)	99.0	100.5 %
pH (NF: 1 in 25)	3.5	5.5
pH (EP: 1 in 30)	3.5	5.5
LOSS ON DRYING		2.5 %
LOSS ON IGNITION (NF)		2.0 %
LOSS ON IGNITION (EP)		5.0 %
ARSENIC		8 ppm
CHLORIDES		250 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		
MONOGRAPH EDITION.		

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 Analysis

Item Number	S1510	Lot Number	1KE0856
Item	Colloidal Silicon Dioxide, NF, EP		
CAS Number	7631-86-9		
Molecular Formula	SiO_2	Molecular Weight	60.08

Test	Specification		Result
	min	max	
ASSAY (IGNITED BASIS)	99.0	100.5 %	99.9 %
pH (NF: 1 in 25)	3.5	5.5	4.1
pH (EP: 1 in 30)	3.5	5.5	4.2
LOSS ON DRYING		2.5 %	0.5 %
LOSS ON IGNITION (NF)		2.0 %	0.5 %
LOSS ON IGNITION (EP)		5.0 %	0.9 %
ARSENIC		8 ppm	<8 ppm
CHLORIDES		250 ppm	<250 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			23-JAN-2023
DATE OF MANUFACTURE			24-JAN-2021
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(NF) 38
MONOGRAPH EDITION.			(EP) 10

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

Certificate of Analysis Results Certified By:

Jigisha Patel
VP Regulatory Compliance & Technical Services, Regulatory

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.

SAFETY DATA SHEET

Preparation Date: 12/10/2015 **Revision Date:** 8/9/2018 **Revision Number:** G2

1. IDENTIFICATION

Product identifier

Product code: S1510
Product Name: Colloidal Silicon Dioxide

Other means of identification

Synonyms: Silicon Dioxide, chemically prepared.
Synthetic amorphous silica, not to be confused with crystalline silica such as quartz, cristobalite, or tridymite or with diatomaceous earth or other naturally occuring forms of amorphous silica that frequently contain crystalline forms
Dioxyde de silicium, préparé chimiquement.
Silice amorphe synthétique, qui ne doit pas être confondu avec la silice cristalline telle que le quartz, la cristobalite ou la tridymite ou avec la terre de diatomées ou d'autres formes naturelles de silice amorphe contenant fréquemment des formes cristallines (French)
CAS #: 7631-86-9
RTECS # VV7565000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Anti-caking agent. Thickening agent. Dental abrasive in toothpaste. Ceramics. Opacifying agent. In printing inks. Insulation material. Adhesives. Cosmetics.
Uses advised against No information available

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 not considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Colloidal Silicon Dioxide	7631-86-9	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 irritation develops.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. In case of shortness of breath, give oxygen. Obtain medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin irritation

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: The product is not flammable. If it is involved in a fire, extinguish the fire using an agent suitable for the type of surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: No information available.

Specific hazards: No information available.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment.

Environmental precautions No information available.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:
Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

Safe Handling Advice
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. 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:
Hygroscopic. Protect from moisture. 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:
Hydrogen fluoride
Hydrofluoric acid
Chlorine trifluoride
Oxygen difluoride

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Colloidal Silicon Dioxide	7631-86-9	20mppcfTWA (80)/(% SiO2) mg/m³ TWA	6 mg/m³ TWA	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Colloidal Silicon Dioxide	7631-86-9	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Colloidal Silicon Dioxide	7631-86-9	2 mg/m³ TWA	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Safety glasses with side-shields or Goggles

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

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Solid

Appearance:
Powder.

Color:
White.

Odor:
Odorless.

Taste
Tasteless.

Formula:
SiO2

Molecular/Formula weight (g/mole):
60.08

Flammability:
No information available

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

Flash Point Tested according to:
Not applicable

Autoignition Temperature (°C/°F):
No information available

Lower Explosion Limit (%):
No information available

Upper Explosion Limit (%):
No information available

Melting point/range(°C/°F):
1710 °C/3110 °F

Decomposition temperature(°C/°F):
No information available

Boiling point/range(°C/°F):
2230 °C/4046 °F

Bulk density:
No information available

Density (g/cm3):
No information available

Specific gravity:
2.1-2.2

pH:
No information available

Vapor pressure @ 20°C (kPa):
No information available

Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

Partition coefficient (n-octanol/water):
No information available

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Insoluble in water
Insoluble in Ethanol
Very Slightly soluble in alkali
Soluble in hot KOH or NaOH solutions
Insoluble in acids except hydrofluoric acid

10. STABILITY AND REACTIVITY

Reactivity
Vinyl acetate vapor may react vigorously in contact with Silica gel
Reactive with hydrogen fluoride (hydrofluoric acid), oxygen difluoride, chlorine trifluoride. May react vigorously with vinyl acetate vapor

Chemical stability

Stability: Hygroscopic. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials. Exposure to moist air. Exposure to moisture.

Incompatible Materials:
Hydrogen fluoride
Hydrofluoric acid
Chlorine trifluoride
Oxygen difluoride

Hazardous decomposition products: No information available.

Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Colloidal Silicon Dioxide	
CAS-No.	7631-86-9

LD50/oral/rat = 7900 mg/kg Oral LD50 Rat
LD50/oral/mouse = No information available
LD50/dermal/rabbit = >2000 mg/kg
LD50/dermal/rat = No information available
LC50/inhalation/rat = >2.2 mg/L 1 h
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = > 5000 mg/kg

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

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = > 2000 mg/kg

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 = >2.2 mg/l (1-hr)

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:	May cause skin irritation. May cause dryness of the skin in cases of severe exposure.
Eye Contact:	May cause eye irritation. May cause irritation of the eyes by mechanical action.
Inhalation	May cause irritation of respiratory tract. May cause dryness and irritation to mucous membranes and respiratory tract in cases of severe exposure.
Ingestion	Health injuries are not known or expected under normal use. Not expected to be a health hazard.
Aspiration hazard	No information available.

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

Chronic Toxicity	Repeated or prolonged skin contact may cause dryness and cracking of the skin.

Chronic inhalation of Amorphous silica may rarely cause Silicosis, Pneumoconiosis, bronchitis, emphysema, asthma. Symptoms may include cough, and dfficulty breathing and shortness of breath (dyspnea). One case suggests a potentilal link between occupational exposure to silica and bronchiolitis obliterans.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not classifiable as to its carcinogenicity to humans.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Colloidal Silicon Dioxide	7631-86-9	Group 1 - Carcinogenic - Monograph 68 [1997] Supplement 7 [1987](for crystalline silica only)	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)
Group 3 - Not classifiable as to its carcinogenicity to humans
NTP (National Toxicology Program)

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

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Colloidal Silicon Dioxide - 7631-86-9
Freshwater Algae Data: 440 mg/L EC50 Pseudokirchneriella subcapitata 72 h
Freshwater Fish Species Data: 5000 mg/L LC50 Brachydanio rerio 96 h static 1
Water Flea Data: 7600 mg/L EC50 Ceriodaphnia dubia 48 h

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
Colloidal Silicon Dioxide	7631-86-9	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

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Colloidal Silicon Dioxide	7631-86-9	PresentACTIVE	Present KE-31032	Present	Present (1)-548	Present	Present	Present 231-545-4

U.S. Regulations

Colloidal Silicon Dioxide
Massachusetts RTK: Present
Pennsylvania RTK: Present
Minnesota - Hazardous Substance List: Present
California Directors List of Hazardous Substances: Present
FDA - Direct Food Additives 21 CFR 172.230, 21 CFR 172.480, 21 CFR 173.340
FDA - 21 CFR - Total Food Additives 160.105, 160.185, 172.230, 172.480, 173.340, 175.105, 175.300, 175.320, 176.170, 176.180, 176.200, 176.210, 177.1200, 177.2250, 177.2420, 177.2600, 178.3297, 182.90, 73.1, 73.575

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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Colloidal Silicon Dioxide	7631-86-9	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

Colloidal Silicon Dioxide	7631-86-9	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**
Colloidal Silicon Dioxide	7631-86-9	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: Not a dangerous product according to HPR classification criteria.

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

WHMIS 1988 Hazard Class
Non-controlled

Components
Colloidal Silicon Dioxide

WHMIS 1988
Uncontrolled product according to WHMIS classification criteria

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.

Components	**WHMIS Ingredient Disclosure List -**
Colloidal Silicon Dioxide	1 %

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Colloidal Silicon Dioxide	7631-86-9	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Colloidal Silicon Dioxide	7631-86-9	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Colloidal Silicon Dioxide	7631-86-9	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Colloidal Silicon Dioxide	7631-86-9	

EU - CLP (1272/2008)

R-phrase(s)

none

S -phrase(s)
none

Components	CAS-No.	**Classification**	**Concentration Limits:**	**Safety Phrases**
Colloidal Silicon Dioxide	7631-86-9		No information	

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

Indication of danger:
Not dangerous

16. OTHER INFORMATION

Preparation Date: 12/10/2015
Revision Date: 8/9/2018
Prepared by: Sonia Owen

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

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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
S1510	Colloidal Silicon Dioxide, NF, EP

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

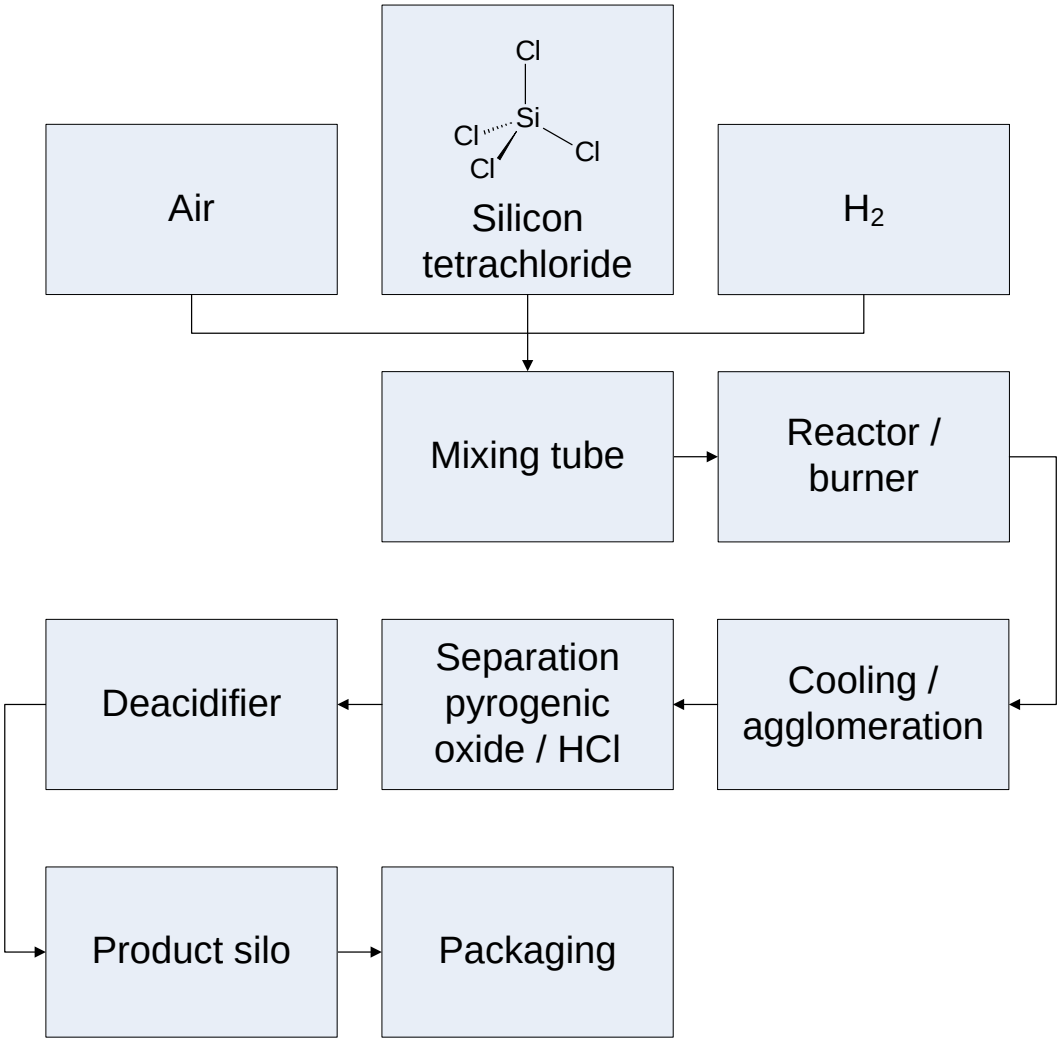
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Colloidal Silicon Dioxide, NF, EP - S1510



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S1510, Colloidal Silicon Dioxide, NF, EP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

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

Allergen Statement

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

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

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 been tested on animals for regulatory compliance purposes.

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 24 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

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

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Pesticides
- Phthalates
- Preservatives

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RE: Elemental Impurities - Colloidal Silicon Dioxide, NF, EP (Cat# S1510)

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
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FAX 310.516.9843

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RE: Residual Solvents - Colloidal Silicon Dioxide, NF, EP (Cat# S1510)

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 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

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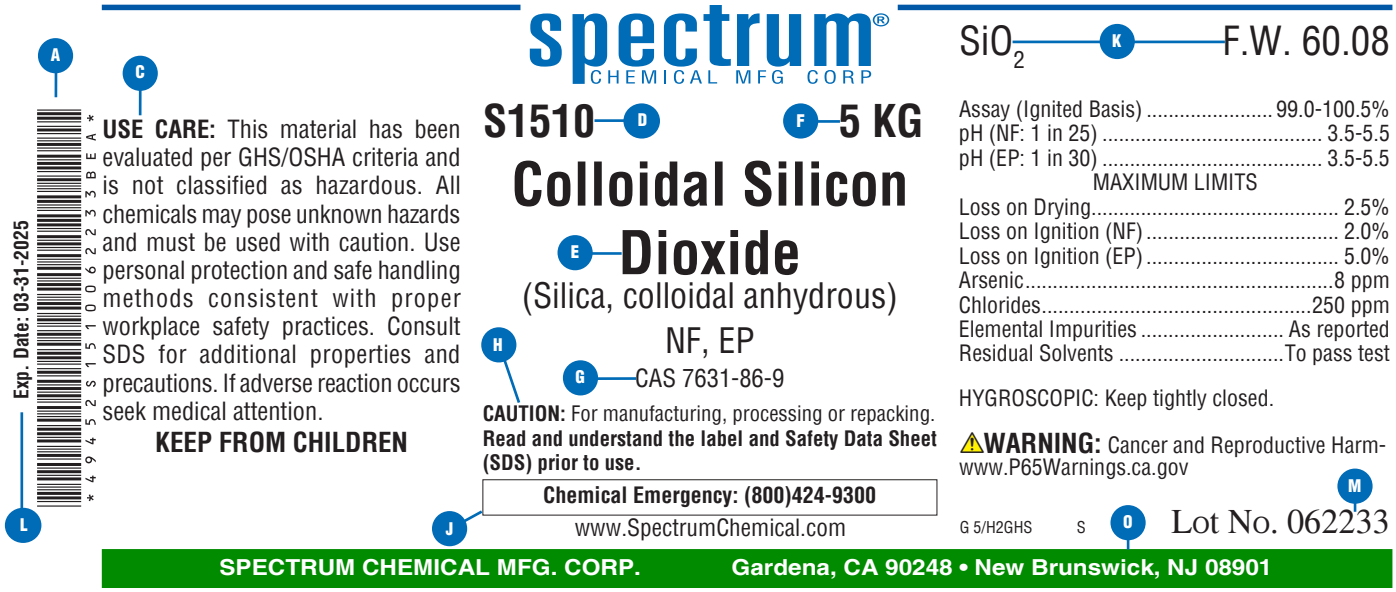
Label Information

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.



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

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

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New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

spectrum®

RE: Lot Numbering System

Dear Valued Customer:

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

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

Example: ZI0928 = The 928th material produced in California in September 2010

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

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

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

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

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