

# Scientific Documentation

## Talc, FCC

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



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Manufacturing Process Flowchart  
Technical Statements  
General Label Information – Sample Label

## Specification for Talc, FCC (T1002)

Item Number	T1002
Item	Talc, FCC
CAS Number	14807-96-6
Molecular Formula	$3\text{MgO} \cdot 4\text{SiO}_2 \cdot \text{H}_2\text{O}$
Molecular Weight	379.29
MDL Number	
Synonyms	Talcum

Test	Specification	
	Min	Max
ACID-SOLUBLE SUBSTANCES (as $\text{SO}_4$ )		2.5 %
ARSENIC (As)		3 mg/kg
FREE ALKALI (as NaOH)		1 %
LEAD (Pb)		5 mg/kg
LOSS ON DRYING		0.5 %
LOSS ON IGNITION		6.0 %
SOLUBLE SALTS		0.2 %
IDENTIFICATION	TO PASS TEST	
CERTIFIED HALAL		
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		

### *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

# Certificate Of Analysis

Item Number	T1002	Lot Number	1MH0161
Item	Talc, FCC	CAS Number	14807-96-6
Molecular Formula	3MgO•4SiO <sub>2</sub> •H <sub>2</sub> O	Molecular Weight	379.29

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ACID-SOLUBLE SUBSTANCES (as SO <sub>4</sub> )		2.5 %	2.0 %
ARSENIC (As)		3 mg/kg	<0.2 mg/kg
FREE ALKALI (as NaOH)		1 %	<1 %
LEAD (Pb)		5 mg/kg	<0.3 mg/kg
LOSS ON DRYING		0.5 %	0.1 %
LOSS ON IGNITION		6.0 %	5.4 %
SOLUBLE SALTS		0.2 %	0.1 %
IDENTIFICATION	TO PASS TEST		PASSES TEST
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			WHITE POWDER
RETEST DATE			21-MAR-2026
DATE OF MANUFACTURE			21-MAR-2023
MONOGRAPH EDITION			(FCC) 13

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
26-OCT-23 07:51:42

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



Certificate of Analysis Results Approved By:

SHANSEN  
Selin Hansen  
27-OCT-23 12:29:11

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.

# SAFETY DATA SHEET

# spectrum®



Revision date 20-May-2022

Revision Number 2

## 1. Identification

### Product identifier

Product Name TALC, FCC

### Other means of identification

Product Code(s) T1002

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

Carcinogenicity	Category 1A
-----------------	-------------

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

Danger

### Hazard statements

May cause cancer



**Appearance** Powder

**Physical state** Solid

**Odor** No information available

**Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

**Precautionary Statements - Storage**

Store locked up.

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Not applicable.

**Mixture**

Chemical name	CAS No	Weight-%	Trade secret
Talc	14807-96-6	80 - 100	*
Silicon Dioxide, crystalline	14808-60-7	1 - <3	*

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

### 4. First-aid measures

**Description of first aid measures**

**General advice**

IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.

**Inhalation**

Remove to fresh air.

**Eye contact**

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

**Skin contact**

Wash skin with soap and water.

**Ingestion**

Clean mouth with water and drink afterwards plenty of water.

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

**Symptoms**

No information available.

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

**Note to physicians** Treat symptomatically.

## **5. Fire-fighting measures**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous combustion products</b>	If it is involved in a fire the following can be released: Silicon oxides. Magnesium oxides.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	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**

<b>Personal precautions</b>	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.

### **Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

### **Precautions for safe handling**

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation.
--------------------------------	--

### **Conditions for safe storage, including any incompatibilities**

<b>Storage Conditions</b>	Keep container tightly closed in a dry and well-ventilated place.
---------------------------	---

## **8. Exposure controls/personal protection**

### **Control parameters**

<b>Exposure Limits</b>	.
------------------------	---

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Talc 14807-96-6	No data available	20mppcfTWAif 1% Quartz or more;use Quartz limit	-
Silicon Dioxide, crystalline 14808-60-7	No data available	50 µg/m <sup>3</sup> TWA (250)/(%SiO <sub>2</sub> + 5) mppcf TWArespirable fraction (10)/(%SiO <sub>2</sub> + 2) mg/m <sup>3</sup> TWArespirable fraction	-

#### 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.

**Hand protection**                              Wear suitable gloves.

**Skin and body protection**                      Wear suitable protective clothing.

**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**                      Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## **9. Physical and chemical properties**

#### Information on basic physical and chemical properties

**Physical state**                                      Solid  
**Appearance**                                      Powder  
**Color**    White; to; Grayish White  
**Odor**    No information available  
**Odor threshold**                                      No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	no data available	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	2.7	None known
<b>Water solubility</b>	Insoluble in water	None known
<b>Solubility(ies)</b>	Insoluble in solvents	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

#### Other information



<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	.
<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	No information available.
-----------------	---------------------------

### Acute toxicity

### Numerical measures of toxicity

### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Silicon Dioxide, crystalline 14808-60-7	500 mg/kg ( Rat )	-	-

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Talc	-	Group 2B - Possibly	-	-

14807-96-6		carcinogenic to humans - Monograph 93 [2010] Supplement 7 [1987] Monograph 42 [1987]		
Silicon Dioxide, crystalline 14808-60-7	-	Group 1 - Monograph 100C [2012] Crystalline silica inhaled in the form of quartz or cristobalite from occupational sources Monograph 68 [1997]	-	-

#### Legend

<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Causes damage to organs through prolonged or repeated exposure.
<b>Target organ effects</b>	respiratory system, Eyes, Central Vascular System (CVS), lungs.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

#### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Talc 14807-96-6	-	LC50: >100g/L (96h, Brachydanio rerio)	-	-

<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.

<b>Other adverse effects</b>	No information available.
------------------------------	---------------------------

## 13. Disposal considerations

#### Waste treatment methods

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

## 14. Transport information

<b>DOT</b>	not regulated
<b>TDG</b>	not regulated
<b>MEX</b>	not regulated
<b>ICAO (air)</b>	not regulated
<b>IATA</b>	not regulated

<b>IMDG</b>	not regulated
<b>RID</b>	not regulated
<b>ADR</b>	not regulated
<b>ADN</b>	not regulated

## 15. Regulatory information

### International Inventories

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

#### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

### US Federal Regulations

#### **SARA 313**

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

#### **SARA 311/312 Hazard Categories**

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

#### **CWA (Clean Water Act)**

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

#### **CERCLA**

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

### US State Regulations

#### **California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
---------------	---------------------------

Silicon Dioxide, crystalline - 14808-60-7	carcinogen
---	------------

## **U.S. State Right-to-Know Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Talc 14807-96-6	1773 4203	Present	Present
Silicon Dioxide, crystalline 14808-60-7	1660	Present	Present

## **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** 1\*

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

*Chronic Hazard Star Legend*

*\* = Chronic Health Hazard*

### **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) (AELG(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** 20-May-2022

**Revision Note** 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
T1002	Talc, FCC

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](mailto:qualityassurance@spectrumchemical.com)

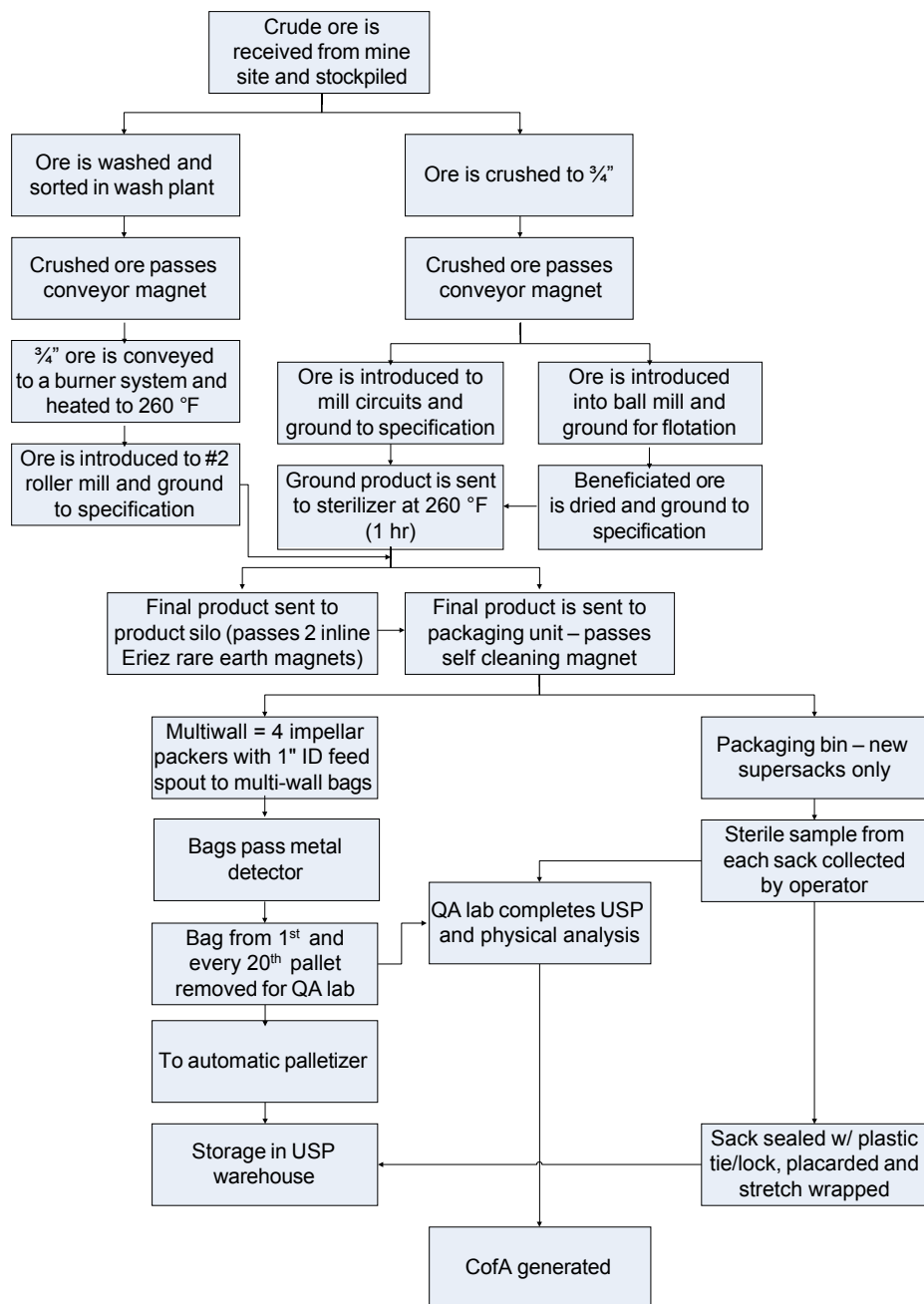
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Talc, FCC - T1002



### 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

## T1002, Talc, FCC

### Source Statement

The above mentioned catalog item is manufactured by purification from natural inorganic material. 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 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |

## 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.




**DANGER**

- May cause cancer.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Wear protective gloves, protective clothing, eye protection, face protection.

**FIRST AID:** If exposed or concerned: Get medical attention.

**KEEP FROM CHILDREN**



**T1002**

**Talc**  
(Talcum)  
F.C.C.  
CAS 14807-96-6

**CAUTION:** For manufacturing, processing or repacking.  
**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)

**3MgO•4SiO<sub>2</sub>•H<sub>2</sub>O**    F.W. 379.29

**SIZ SY**    Asbestos Free.

**MAXIMUM LIMITS**

Acid-Soluble Substances (as SO <sub>4</sub> )	.....2.5%
Arsenic (as As)	.....3 mg/kg
Free Alkali (as NaOH)	.....1%
Lead	.....5 mg/kg
Loss on Drying	.....0.5%
Loss on Ignition	.....6.0%
Soluble Salts	.....0.2%

**WARNING:** Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

G 5/G5GHS    ?    Lot No. XQ####

### 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