

# Scientific Documentation

## Cellulose Gum, Low Viscosity, 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



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# Specification for Cellulose Gum, Low Viscosity, FCC (C1103)

Item Number	C1103
Item	Cellulose Gum, Low Viscosity, FCC
CAS Number	9004-32-4
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Sodium Carboxymethylcellulose ; Base H ; Carmellose Sodium ; Cellulose, Carboxymethyl Ether Sodium Salt

Test	Specification	
	Min	Max
ASSAY (CELLULOSE GUM; DRIED BASIS)	99.5	100.5 %
DEGREE OF SUBSTITUTION(CARBOXYMETHYL GROUPS PER ANHYDROGLUCOSE UNIT;DRIED BASIS)	0.2	1.5
LEAD		2 mg/kg
LOSS ON DRYING		10.0 %
SODIUM (DRIED BASIS)		12.4 %
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
MONOGRAPH EDITION		

## *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	C1103	Lot Number	2MH0121
Item	Cellulose Gum, Low Viscosity, FCC	CAS Number	9004-32-4

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (CELLULOSE GUM; DRIED BASIS)	99.5	100.5 %	99.7 %
DEGREE OF SUBSTITUTION(CARBOXYMETHYL GROUPS PER ANHYDROGLUCOSE UNIT;DRIED BASIS)	0.2	1.5	0.74
LEAD		2 mg/kg	<2 mg/kg
LOSS ON DRYING		10.0 %	3.8 %
SODIUM (DRIED BASIS)		12.4 %	7.7 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			OFF-WHITE POWDER
RETEST DATE			02-APR-2024
DATE OF MANUFACTURE			03-APR-2023
MONOGRAPH EDITION			FCC 13

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
01-SEP-23 08:36:28

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

GHERRERA  
Genaro Herrera  
07-SEP-23 09:11:57

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 14-April-2024



Revision Number 3

## 1. Identification

### Product identifier

**Product Name** CELLULOSE GUM, LOW VISCOSITY, FCC

### Other means of identification

**Product Code(s)** C1103

**Synonyms** None

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

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### **Supplier Address**

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

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

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

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### **Hazard statements**

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

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

**Appearance** powder or granules

**Physical state** Solid

**Odor** No information available

**Other information**

No information available.

**3. Composition/information on ingredients****Substance**

Chemical name	CAS No	Weight-%
Carboxymethylcellulose Sodium	9004-32-4	100

**4. First-aid measures****Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water for at least 15 minutes. If symptoms persist, call a physician.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
<b>Self-protection of the first aider</b>	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid contact with skin, eyes or clothing.

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

<b>Symptoms</b>	May cause redness and tearing of the eyes. Burning sensation.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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**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>	Carbon Monoxide, Carbon Dioxide.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.

**Sensitivity to static discharge** none.

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **6. Accidental release measures**

### **Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

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

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

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

### **Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

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

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

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

### **Control parameters**

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### **Appropriate engineering controls**

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

### **Individual protection measures, such as personal protective equipment**

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves. Impervious gloves.

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

<b>General hygiene considerations</b>	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.
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## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	powder or granules
<b>Color</b>	White to Cream
<b>Odor</b>	No information available
<b>Odor threshold</b>	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>	1.6	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	no data available	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>	Strong acids. Strong bases. Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information



### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

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

<b>Symptoms</b>	Redness. May cause redness and tearing of the eyes.
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#### Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Carboxymethylcellulose Sodium 9004-32-4	= 27000 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h

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

<b>Skin corrosion/irritation</b>	Classification based on data available for ingredients. Irritating to skin.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<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
Carboxymethylcellulose Sodium	-	>20000 mg/l 96 h LC50 ONcorhynchus mykiss	-	87.26 mg/l 48 h EC50 Ceriodaphnia dubia

9004-32-4		(Rainbow Trout) (Ecotox - U.S. EPA)		(Ecotox - U.S. EPA)
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**Persistence and degradability** No information available.

**Bioaccumulation** Inherently biodegradable.

**Other adverse effects** No information available.

### 13. Disposal considerations

#### Waste treatment methods

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

### 14. Transport information

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

IATA not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

### 15. Regulatory information

#### International Inventories

**TSCA** Complies

**DSL/NDSL** Complies  
**EINECS/ELINCS** Does not Comply  
**ENCS** This product complies with ENCS:  
**IECSC** This product complies with China:  
**KECL** Complies  
**PICCS** Complies  
**AICS** 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 does not contain any Proposition 65 chemicals.

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

This product does not contain any substances regulated under applicable state right-to-know regulations

### **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

#### **NFPA**

**Health hazards** 0

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 0

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

#### **Key or legend to abbreviations and acronyms used in the safety data sheet**

##### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### **Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision date** 14-April-2024  
**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
C1103	Cellulose Gum, Low Viscosity, 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,  
Quality Assurance  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

## C1103, Cellulose Gum, Low Viscosity, FCC

### Source Statement

The above-mentioned catalog item is a synthetic polymer derived from plant origin (wood pulp). No animal derived products are used in the manufacturing process.

### BSE/TSE Statement

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

### Allergen Statement

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

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

### 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 the above-mentioned material.

### Animal Testing Statement

The above-mentioned catalog item has been tested on animals.

### Organic Compliance Statement

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

### Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 12 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        | ▪ Pesticides    |
| ▪ Antibiotics       | ▪ Phthalates    |
| ▪ Bisphenol A (BPA) | ▪ 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.

**USE CARE:** This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN**

**C1103**

**SIZ SY**

### Cellulose Gum

(Carmellose Sodium; Cellulose, Carboxymethyl Ether Sodium Salt; Sodium Carboxymethylcellulose)

Low Viscosity, F.C.C.

CAS 9004-32-4

**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)

Assay (Cellulose Gum; Dried Basis) ..... 99.5-100.5%  
Degree of Substitution(Carboxymethyl Groups per Anhydroglucose Unit; Dried Basis) .....0.2-1.5  
**MAXIMUM LIMITS**  
Lead ..... 2 mg/kg  
Loss on Drying ..... 10.0%  
Sodium (Dried Basis) ..... 12.4%

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

G 8/G4GHS

?

Lot No. XQ####

### Spectrum Chemical Mfg Corp

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