

# Scientific Documentation

## Methylcellulose, 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



## **Table of Contents**

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

## Specification for Methylcellulose, USP (M1314)

Item Number	M1314
Item	Methylcellulose, USP
CAS Number	9004-67-5
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Cellulose Methyl Ether ; Modified Cellulose ; MC

Test	Specification	
	Min	Max
ASSAY, DRIED BASIS (METHOXY GROUPS: -OCH <sub>3</sub> )	26.0	33.0 %
pH	5.0	8.0
VISCOSITY	12	18 cP
LOSS ON DRYING		5.0 %
RESIDUE ON IGNITION		1.5 %
ELEMENTAL IMPURITIES:		
NICKEL (Ni)		AS REPORTED
CHROMIUM (Cr)		AS REPORTED
IDENTIFICATION		TO PASS TEST
CERTIFIED HALAL		
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

### *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	M1314	Lot Number	1MA0112
Item	Methylcellulose, USP	CAS Number	9004-67-5

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY, DRIED BASIS (METHOXY GROUPS: -OCH <sub>3</sub> )	26.0	33.0 %	28.3 %
pH	5.0	8.0	6.9
VISCOSITY	12	18 cP	17.3 cP
LOSS ON DRYING		5.0 %	2.05 %
RESIDUE ON IGNITION		1.5 %	0.7 %
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
IDENTIFICATION		TO PASS TEST	PASSES TEST
CERTIFIED HALAL			CERTIFIED HALAL
RETEST DATE			12-DEC-2025
DATE OF MANUFACTURE			13-DEC-2022
APPEARANCE			OFF-WHITE POWDER
RESIDUAL SOLVENTS		TO PASS TEST	NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 2022

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
06-FEB-23 16:58:58

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



Certificate of Analysis Results Approved By:

JRUIZ  
Jesus Ruiz  
07-FEB-23 08:15:58

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

# spectrum®



Revision date 24-August-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** METHYLCELLULOSE, 15 CPS, USP

### Other means of identification

**Product Code(s)** M1314

**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

Combustible dust	Yes
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

May form combustible dust concentrations in air

**Appearance** granules or Powder

**Physical state** Solid

**Odor** No information available

### **Precautionary Statements - Prevention**

Keep away from all ignition sources including heat, sparks, and flame  
Keep container closed and grounded  
Prevent dust accumulations to minimize explosion hazard

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Methylcellulose, 15 cps	9004-67-5	100	*

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

### 4. First-aid measures

**Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

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

Symptoms	No information available.
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**Indication of any immediate medical attention and special treatment needed**

Note to physicians	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>	Avoid generation of dust. Fine dust dispersed in air may ignite.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	yes.
<b>Special protective equipment for</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout

fire-fighters

gear. Use personal protection equipment.

## **6. Accidental release measures**

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

<b>Personal precautions</b>	Ensure adequate ventilation. Avoid generation of dust. Avoid contact with eyes. Use personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharges.
<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. Prevent dust cloud.
<b>Methods for cleaning up</b>	Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. 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. Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures against static discharges.
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### **Conditions for safe storage, including any incompatibilities**

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.
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## **8. Exposure controls/personal protection**

### **Control parameters**

<b>Exposure Limits</b>	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.
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### **Appropriate engineering controls**

<b>Engineering controls</b>	Showers Eyewash stations Ventilation systems.
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### **Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
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<b>Skin and body protection</b>	No special protective equipment required.
<b>Respiratory protection</b>	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>	Do not breathe dust.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	granules or Powder
<b>Color</b>	White to Off-White
<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>	>290 °C / °F	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>	no data available	None known
<b>Water solubility</b>	Slowly soluble in cold water	None known
<b>Solubility(ies)</b>	Insoluble in Chloroform	None known
	Insoluble in Ether	
	Insoluble in Alcohol	
<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>	Excessive heat. Heating in air. dust formation.
<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

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

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

Symptoms	No information available.
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### Acute toxicity

#### Numerical measures of toxicity

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

## 12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
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	Dispose of in accordance with local regulations. Dispose of waste in accordance with
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<b>products</b>	environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

<b><u>DOT</u></b>	not regulated
<b><u>TDG</u></b>	not regulated
<b><u>MEX</u></b>	not regulated
<b><u>ICAO (air)</u></b>	not regulated
<b><u>IATA</u></b>	not regulated
<b><u>IMDG</u></b>	not regulated
<b><u>RID</u></b>	not regulated
<b><u>ADR</u></b>	not regulated
<b><u>ADN</u></b>	not regulated

## 15. Regulatory information

### International Inventories

<b>TSCA</b>	Complies
<b>DSL/NDL</b>	Complies
<b>EINECS/ELINCS</b>	Does not Comply
<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/NDL** - 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** 1

**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**

24-August-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
M1314	Methylcellulose, 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

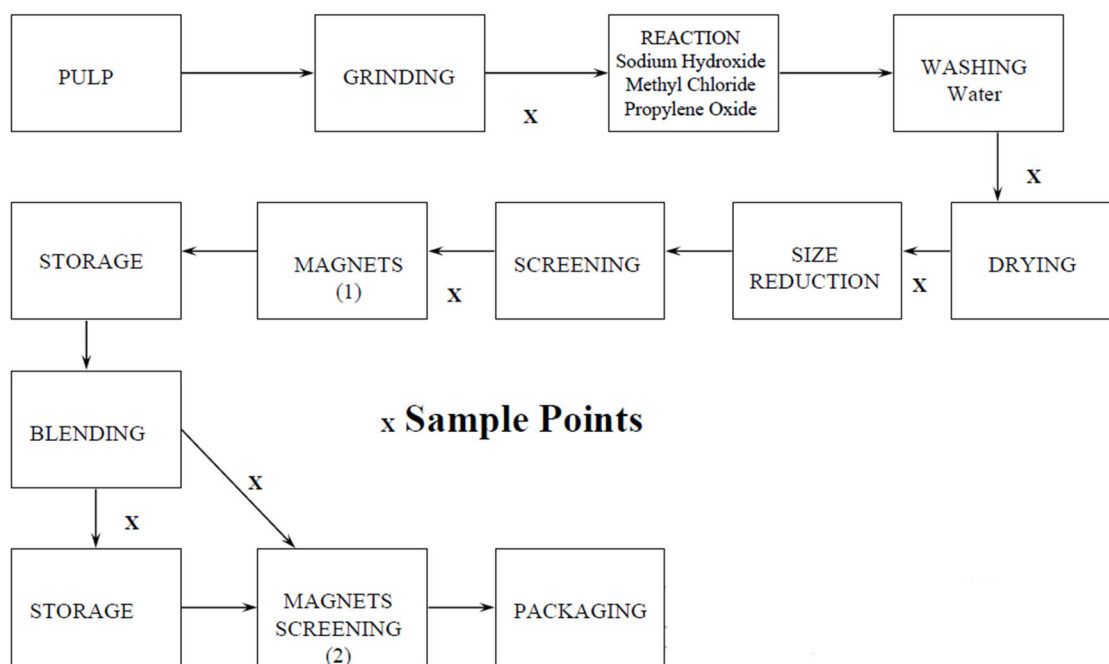
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Methylcellulose, USP (Cat# M1314)



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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

## M1314, Methylcellulose, USP

### Source Statement

The above mentioned catalog item is manufactured from plant origin (cellulose polymer from wood pulp and/or cotton linters). 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
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### GMO Statement

The above mentioned catalog item is manufactured from wood pulp and/or cotton linters. The raw material supplier is unable to confirm that the cotton linters used in the production are not produced from GMOs.

### 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 last been tested on animals in 1973.

## **Organic Compliance Statement**

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

## **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:

- |                     |                 |
|---------------------|-----------------|
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |
| • Parabens          |                 |



**RE: Elemental Impurities - Methylcellulose, USP (Cat# M1314)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Nickel	Ni	2A	< 10 ppm
Chromium	Cr	3	< 550 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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](mailto: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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**RE: Residual Solvents - Methylcellulose, USP (Cat# M1314)**

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](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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## Label Information

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

**WARNING**

- May form combustible dust concentrations in air.
- Keep away from all ignition sources including heat, sparks and flame • Keep container closed and grounded • Prevent dust accumulations to minimize explosion hazard.

This material has been evaluated per GHS criteria and is not classified as hazardous under GHS. 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**

**M1314**

**SIZ SY**

**Methylcellulose**  
(Cellulose Methyl Ether; MC; Modified Cellulose)

USP  
CAS 9004-67-5

**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

Assay, Dried Basis  
(Methoxy Groups: -OCH<sub>3</sub>) ..... 26.0-33.0%  
pH ..... 5.0-8.0  
Viscosity ..... 12-18 cP

**MAXIMUM LIMITS**

Loss on Drying ..... 5.0%  
Residue on Ignition ..... 1.5%  
Elemental Impurities ..... As reported  
Residual Solvents ..... To pass test

**WARNING:** Cancer and Reproductive Harm-  
www.P65Warnings.ca.gov

G 11/J9GHS ?

Lot No. XQ####

### Spectrum Chemical Mfg Corp

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