

Scientific Documentation

Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP

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
Phone 732.214.1300



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Specification for Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP (H1136)

Item Number	H1136
Item	Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP
CAS Number	9004-65-3
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Hydroxypropyl Methylcellulose; Propylene Glycol Ether of Methylcellulose; Modified Cellulose; HPMC; Methocel K100M Premium CR ; Hydroxypropyl Methylcellulose ; Methocel K100M Premium CR

Test	Specification	
	Min	Max
VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C	75,000	140,000 mPa.s
ASSAY (METHOXY GROUPS)	19.0	24.0 %
ASSAY (HYDROXYPROPOXY GROUPS)	4.0	12.0 %
pH	5.0	8.0
LOSS ON DRYING		5.0 %
RESIDUE ON IGNITION		1.5 %
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

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	H1136	Lot Number	1KE0264
Item	Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP	CAS Number	9004-65-3

TEST	SPECIFICATION		RESULT
	MIN	MAX	
VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C	75,000	140,000 mPa.s	120,711
ASSAY (METHOXY GROUPS)	19.0	24.0 %	22.6 %
ASSAY (HYDROXYPROPOXY GROUPS)	4.0	12.0 %	10.6 %
pH	5.0	8.0	6.8
LOSS ON DRYING		5.0 %	2.7 %
RESIDUE ON IGNITION		1.5 %	0.7 %
ELEMENTAL IMPURITIES:			.
NICKEL (Ni)	AS REPORTED		<1.1 µg/g
CHROMIUM (Cr)	AS REPORTED		<0.28 µg/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			WHITE POWDER
RETEST DATE			07-SEP-2025
DATE OF MANUFACTURE			08-SEP-2020
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 43

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
01-JUN-21 16:37:22

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



Certificate of Analysis Results Approved By:

HBERMUDEZ
Hernan Bermudez
01-JUN-21 16:37:34

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: 8/29/2014

Revision Date: 9/25/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: H1136
Product Name: HYPROMELLOSE 2208, 100,000 CPS, CR, USP

Other means of identification

Synonyms: HMPC; Hydroxypropyl Methylcellulose; Hypromellose; Propylene Glycol Ether of Methylcellulose SubstitutionType 2208
CAS #: 9004-65-3
RTECS # NF9125000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
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 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)

Combustible dust	-
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Label elements

Warning

May form combustible dust concentrations in air

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Product code: H1136

Product name: HYPROMELLOSE
2208, 100,000 CPS, CR, USP

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Hypromellose 2208, 100,000 cps	9004-65-3	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. Get 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 Health injuries are not known or expected under normal use
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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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:	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide.
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Specific hazards:	May be combustible at high temperatures. Avoid generating dust. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
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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. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition. Avoid dust formation. Avoid dispersal of dust in the air. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Non-sparking tools should be used.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

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. Minimize dust generation and accumulation. Avoid dust formation. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. All equipment used when handling the product must be grounded. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. 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:

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:

Oxidizing agents
Acids
Bases

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

Product code: H1136

Product name: HYPROMELLOSE
2208, 100,000 CPS, CR, USP

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United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Hypromellose 2208, 100,000 cps	9004-65-3	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Hypromellose 2208, 100,000 cps	9004-65-3	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Hypromellose 2208, 100,000 cps	9004-65-3	None	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. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment) It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment

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. 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. Off-white.
Odor: Odorless.	Taste No information available.	Formula: No information available
Molecular/Formula weight (g/mole): No information available	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	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: Soluble in Water	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents
Reacts with strong bases
Reactive with strong acids

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.

Incompatible Materials: Oxidizing agents
Acids
Bases

Hazardous decomposition products: Carbon monoxide. Carbon dioxide.

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

Hypromellose 2208, 100,000 cps	
CAS-No.	9004-65-3

LD50/oral/rat = >10000 mg/kg

LD50/oral/mouse = No information available

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = > 10000 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = No information available

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Health injuries are not known or expected under normal use. May cause hypermotility, diarrhea.

Aspiration hazard No information available.

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

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Hypromellose 2208, 100,000 cps	9004-65-3	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

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

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Product code: H1136

Product name: HYPROMELLOSE
2208, 100,000 CPS, CR, USP

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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
Hypromellose 2208, 100,000 cps	9004-65-3	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.
<i>Hypromellose 2208, 100,000 cps</i>	9004-65-3	PresentACTIVE	Present KE-05368	Present	Present (8)-196	Present	Present	Not present

U.S. Regulations

Hypromellose 2208, 100,000 cps

FDA - Direct Food Additives 21 CFR 172.874

FDA - 21 CFR - Total Food Additives 172.874, 175.105, 175.300, 177.1960

- List Sourced from EAFUS

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:
<i>Hypromellose 2208, 100,000 cps</i>	9004-65-3	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
<i>Hypromellose 2208, 100,000 cps</i>	9004-65-3	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
<i>Hypromellose 2208, 100,000 cps</i>	9004-65-3	Not Applicable	Not Applicable

Canada

Product code: H1136

Product name: HYPROMELLOSE
2208, 100,000 CPS, CR, USP

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WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

Component
Hypromellose 2208, 100,000 cps
9004-65-3 (100)

WHMIS 2015 Hazard Classification
Combustible Dust - Category 1: May form combustible dust concentrations in air (factors such as combustibility and explosiveness of dusts including composition and shape and size of particles could cause substance to belong to 'Combustible dust' hazard class)

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

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Hypromellose 2208, 100,000 cps	9004-65-3	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Hypromellose 2208, 100,000 cps	9004-65-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Hypromellose 2208, 100,000 cps	9004-65-3	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Hypromellose 2208, 100,000 cps	9004-65-3	

EU - CLP (1272/2008)

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Hypromellose 2208, 100,000 cps	9004-65-3		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: 8/29/2014
Revision Date: 9/25/2018
Prepared by: Sonia Owen

Product code: H1136

Product name: HYPROMELLOSE
2208, 100,000 CPS, CR, USP

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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



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
H1136	Hypromellose, Substitution Type 2208, 100,000 mPa.s, 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

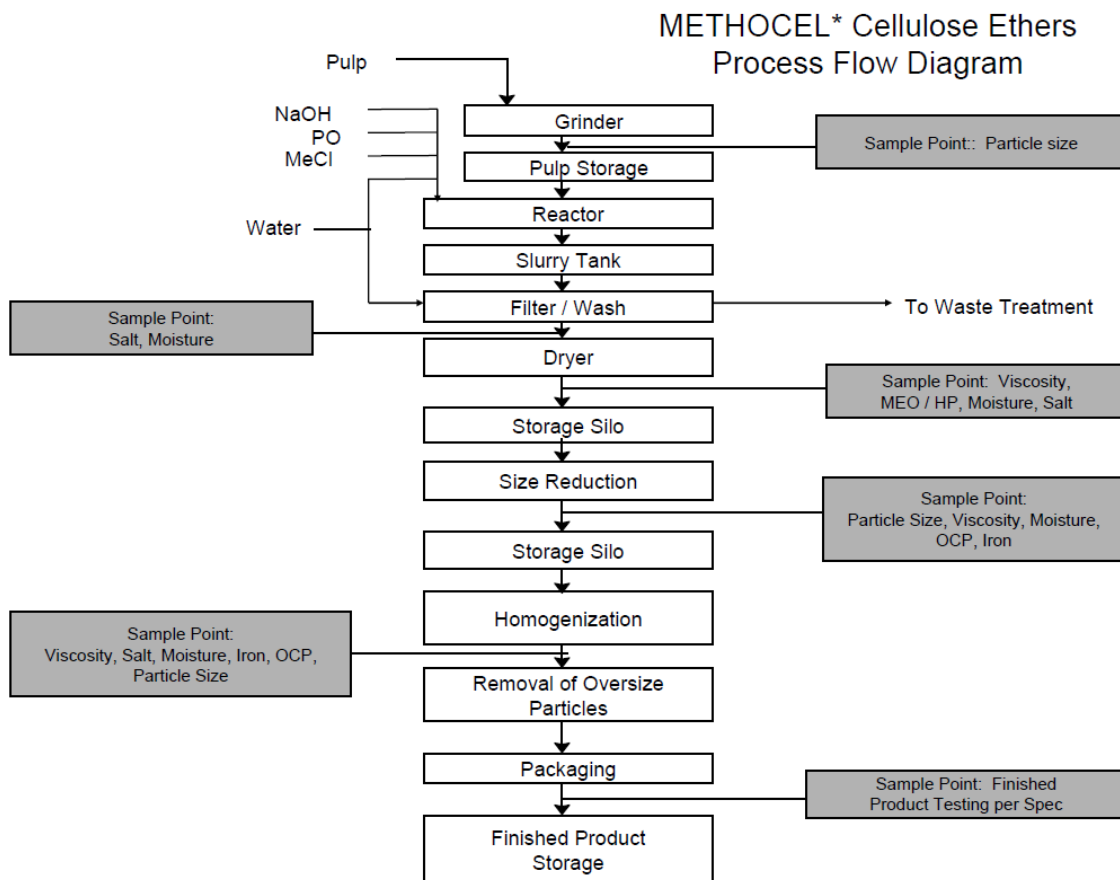
Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP (Cat# H1136)



CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
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FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

H1136, Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis using plant derived material (Cellulose from 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
- 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 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 before 1984.

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 60 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 |



RE: Elemental Impurities - Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP (Cat# H1136)

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.

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
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WEST COAST FACILITY

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RE: Residual Solvents - Hypromellose, Substitution Type 2208, 100,000 mPa.s, USP (Cat# H1136)

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

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

Retest Date: 00-00-0000



H1136 **SIZ SY**
Hypromellose
 (Hydroxypropyl Methylcellulose; Propylene Glycol Ether of Methylcellulose; Modified Cellulose; HPMC: Methocel® K100M Premium CR)
 Substitution Type 2208
 100,000 mPa·s
 USP
 CAS 9004-65-3

CAUTION: For manufacturing, processing or repackaging. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

Particle size suitable for controlled-release coatings. Methocel® is a registered trademark of Dow Wolff Cellulosics.

Viscosity of a 2% Aqueous Solution @ 20°C 75,000-140,000 mPa·s

Assay:
 Methoxy Groups 19.0-24.0%
 Hydroxypropoxy Groups 4.0-12.0%
 pH (2% w/w Aqueous Solution @ 25°C) 5.0-8.0

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 5/J11GHS ? Lot No. XQ####

Spectrum Chemical Mfg Corp

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