

# **Scientific Documentation**

# Hypromellose, Substitution Type 2208, 3,550 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, 3,550 mPa.s, USP (HY124)

Item Number	HY124
Item	Hypromellose, Substitution Type 2208, 3,550 mPa.s, USP
CAS Number	9004-65-3
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Methocel K4M ; Hydroxypropyl Methylcellulose ; Modified Cellulose ; HPMC ; Propylene Glycol Ether of Methylcellulose ; Methocel K100M Premium CR

Test	Specification		
	Min	Max	
APPEARANCE			
IDENTIFICATION (A)	POWDERED MATERIAL AGGREGATES		
IDENTIFICATION (B)	CLEAR OR SLIGHTLY TURBID VISCOUS SOLUTION		
IDENTIFICATION (C)	RED COLOR CHANGES TO PURPLE		
IDENTIFICATION (D)	COHERENT CLEAR FILM FORMS		
IDENTIFICATION (E)	50°C		
VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C	2663 - 4970 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		

Test	Specification		
	Min	Max	
CHROMIUM (Cr)	AS REPORTED		
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 08901Gardena, CA 90248

732.214.1300 310.516.8000



# **Certificate Of Analysis**

Item Number	HY124	Lot Number	1NA0097
Item	Hypromellose, Substitution Type 2208, 3,550 mPa.s, USP	CAS Number	9004-65-3

TECT	SPECIF	ICATION	DECLUIT.
TEST	MIN	MAX	RESULT
APPEARANCE			WHITE POWDER
IDENTIFICATION (A)	POWDERED MATERIAL AGGREGATES		POWDERED MATERIAL AGGREGATES
IDENTIFICATION (B)	CLEAR OR SLIGHTLY TURBID VISCOUS SOLUTION		CLEAR OR SLIGHTLY TURBID VISCOUS SOLUTION
IDENTIFICATION (C)	RED COLOR CHANGES TO PURPLE		RED COLOR CHANGES TO PURPLE
IDENTIFICATION (D)	COHERENT CLEAR FILM FORMS		COHERENT CLEAR FILM FORMS
IDENTIFICATION (E)	50°C		62°C
VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C	2663 - 4970 mPa·s		3600 mPa·s
ASSAY (METHOXY GROUPS)	19.0	24.0%	22.7 %
ASSAY (HYDROXYPROPOXY GROUPS)	4.0	12.0%	7.8 %
рН	5.0	8.0	6.1
LOSS ON DRYING		5.0%	1.3 %
RESIDUE ON IGNITION		1.5%	0.5 %
ELEMENTAL IMPURITIES:			
NICKEL (Ni)	AS REPORTED		1.1 μg/g
CHROMIUM (Cr)	AS REPORTED		0.28 μg/g
RETEST DATE			18-APR-2028
DATE OF MANUFACTURE			20-APR-2023

TECT	SPECIFI	CATION	DECLUT
TEST	MIN	MAX	RESULT
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 19-JAN-24 16:42:37

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 22-JAN-24 09:51:46

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.





Revision date 06-May-2020 Revision Number 2

#### 1. Identification

**Product identifier** 

Product Name HYPROMELLOSE, 2208, 4,000 MPA·S, USP

Other means of identification

Product Code(s) HY124

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

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

#### Hazard statements

May form combustible dust concentrations in air

Appearance Powder Physical state Solid Odor Odorless

#### Other information

No information available.

# 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Hypromellose 2208, 4000 cps	9004-65-3	100	*

<sup>\*</sup>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.

Indication of any immediate medical attention and special treatment needed

# 5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

Avoid generation of dust. Fine dust dispersed in air may ignite.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

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 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.

**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. Prevent dust cloud.

Methods for cleaning up 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

Advice on safe handling 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.

Conditions for safe storage, including any incompatibilities

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

Keep out of the reach of children.

## 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).

**Skin and body protection**No special protective equipment required.

 exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not breathe dust.

## 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid Appearance Powder

Color White to Off-White

**Odor** Odorless

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

no data available None known pН Melting point / freezing point no data available None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

No data available None known Vapor pressure Vapor density no data available None known no data available None known Relative density Water solubility Soluble in water None known no data available Solubility(ies) None known Partition coefficient No data available None known **Autoignition temperature** no data available None known **Decomposition temperature** None known

Kinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties

Oxidizing properties

No information available
VOC Content (%)
No information available
Liquid Density
No information available
Bulk density
No information available

#### 10. Stability and reactivity

**Reactivity** No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

**Conditions to avoid** Excessive heat. Heating in air. dust formation.

**Incompatible materials**None known based on information supplied.

Hazardous decomposition products 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.

**Acute toxicity** 

Numerical measures of toxicity

10000

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

Skin corrosion/irritation Serious eye damage/eye irritation

Serious eye damage/eye irritation Respiratory or skin sensitization

Germ cell mutagenicity

No information available.

No information available. No information available. No information available.

Reproductive toxicity No information available.

STOT - single exposure STOT - repeated exposure

Aspiration hazard

Other adverse effects

No information available.

No information available.

No information available.

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

**Bioaccumulation** 

No information available. 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

<u>IMDG</u> 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 IECSC**This product complies with ENCS:
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).

#### Leaend:

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 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 06-May-2020

Revision Note No information available.

<u>Disclaimer</u>
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
HY124	Hypromellose, Substitution Type 2208, 3,550 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,

Oralia Chavez

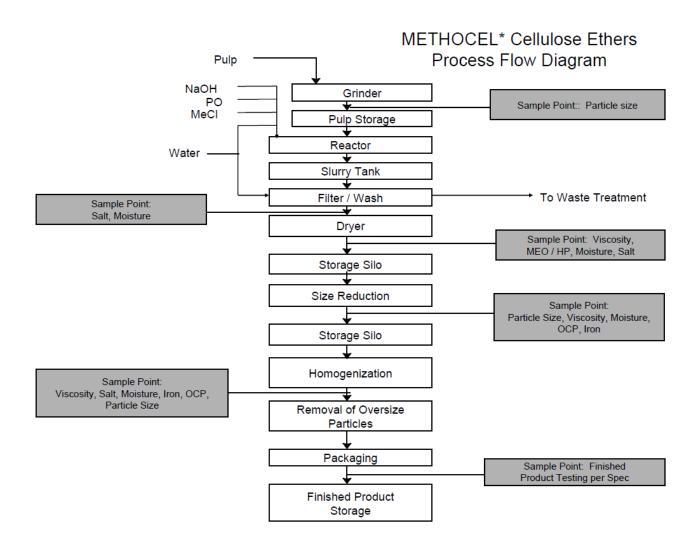
Quality Assurance Specialist

Order Clony



# **Manufacturing Process Flowchart**

Hypromellose, Substitution Type 2208, 3,550 mPa.s, USP (Cat# HY124)



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



# **HY124**, Hypromellose, Substitution Type 2208, 3,550 mPa.s, USP

# **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis using 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 year 1984.

# **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



# RE: Elemental Impurities - Hypromellose, Substitution Type 2208, 3,550 mPa.s, USP (Cat# HY124)

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
Thallium	TI	2B	Not tested
Gold	Au	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	Not tested
Barium	Ва	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	< 550 ppm

Elements indicated as "Not tested" are not intentionally added to the manufacturing process

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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



# RE: Residual Solvents - Hypromellose, Substitution Type 2208, 3,550 mPa.s, USP (Cat# HY124)

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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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# **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

0000-00-00

#### 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** 

# HY124 SIZ SY **Hypromellose**

(HPMC; Hydroxypropyl Methylcellulose; Modified Cellulose; Propylene Glycol Ether of Methylcellulose)

> Substitution Type 2208 3,550 mPa·s USP

CAS 9004-65-3

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

Viscosity of a 2% Aqueous Solution2,6	
Assay: Methoxy Groups Hydroxypropoxy Groups	
pHMAXIMUM LIMITS	
Loss on Drying	5.0%
Residue on Ignition	
Elemental Impurities	
Residual Solvents	10 pass test

**WARNING:** Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 12/J10GHS ? Lot No. XQ####

# Spectrum Chemical Mfg Corp

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