

### **Scientific Documentation**

# Hypromellose, Substitution Type 2910, 4000 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 2910, 4000 mPa.s, USP (H1128)

Item Number	H1128
Item	Hypromellose, Substitution Type 2910, 4000 mPa.s, USP
CAS Number	9004-65-3
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Modified Cellulose ; Methocel E4M Premium CR ; Hydroxypropyl Methylcellulose ; HPMC ; Propylene Glycol Ether of Methylcellulose

Test	Specification		
	Min	Max	
VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C	3,000	5,600 mPa·s	
ASSAY (METHOXY GROUPS)	28.0	30.0%	
ASSAY:HYDROXYPROPOXY GROUPS	7.0	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		
RETEST DATE			
MANUFACTURE DATE			
APPEARANCE			
RESIDUAL SOLVENTS	TO PASS TEST		

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

769 Jersey Ave.

14422 S. San Pedro St.

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



## **Certificate Of Analysis**

Item Number	H1128	Lot Number	2MK0246
Item	Hypromellose, Substitution Type 2910, 4000 mPa.s, USP	CAS Number	9004-65-3

TECT	SPECIFICATION		DECLUT
TEST	MIN	MAX	RESULT
VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C	3,000	5,600 mPa·s	4929mPa·s
ASSAY (METHOXY GROUPS)	28.0	30.0%	28.8 %
ASSAY:HYDROXYPROPOXY GROUPS	7.0	12.0%	9.3 %
рН	5.0	8.0	6.1
LOSS ON DRYING		5.0%	0.9 %
RESIDUE ON IGNITION		1.5%	0.2 %
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
NICKEL (Ni)	AS REPORTED		<10 ppm
CHROMIUM (Cr)	AS REPORTED		<550 ppm
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			28-OCT-2027
MANUFACTURE DATE			29-OCT-2022
APPEARANCE			OFF-WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		NO RESIDUAL SOLVENT PRESENT
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA Genaro Herrera 11-DEC-23 13:18:59

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO Matheu Camacho 12-DEC-23 06:50:57 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.

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 19-May-2022 Revision Number 2

#### 1. Identification

**Product identifier** 

Product Name HYPROMELLOSE 2910, 4000 CPS, CR, USP

Other means of identification

Product Code(s) H1128

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use In pharmaceuticals. Industrial. Binder

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).

Combustible dust Yes

#### 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). May form combustible dust concentrations in air

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Hypromellose 2910, 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

No information available.

Hazardous combustion products Carbon dioxide (CO2).

**Explosion data** 

Sensitivity to mechanical impact 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** Ensure adequate ventilation.

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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

#### 8. Exposure controls/personal protection

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

**Appropriate engineering controls** 

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

**Eye/face protection** No special protective equipment required.

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

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

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid Appearance Powder

Color White to Off-White

Odor No information available
Odor threshold No information available

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

pН no data available None known 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 Relative density 1.3 None known Water solubility Soluble in water None known Solubility(ies) no data available None known No data available None known Partition coefficient

Autoignition temperatureno data availableNone knownDecomposition temperatureNone known

Kinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties

Oxidizing properties

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 None known based on information supplied.

**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

**Inhalation** Specific test data for the substance or mixture is not available.

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**

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

Skin corrosion/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 No information available. No information available. 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

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

<u>IATA</u> 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 19-May-2022

**Revision Note**No information available.

**Disclaimer** 

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet** 



#### Certification of Compliance with current Good Manufacturing Practices

#### Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
H1128	Hypromellose, Substitution Type 2910, 4000 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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

**Quality Assurance Specialist** 

Order Clony



# **H1128**, Hypromellose, Substitution Type 2910, 4000 mPa.s, USP

#### **Source Statement**

The above mentioned catalog item is manufactured from plant derived materials (natural cellulose derived 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
- Latex
- Sulfites > 10 ppm

#### **GMO Statement**

The above mentioned catalog item is manufactured from natural cellulose derived from wood pulp and/or cotton linters. We cannot guarantee that the cotton linters used in the production are not produced from genetically modified organisms (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 been tested on animals. Animal Testing was last conducted in 1986.

#### **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:

- Antibiotics
- Bisphenol A (BPA)
- Parabens

- Pesticides
- Phthalates
- Preservatives



## RE: Elemental Impurities - Hypromellose, Substitution Type 2910, 4000 mPa.s, USP (Cat# H1128)

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 <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 2910, 4000 mPa.s, USP (Cat# H1128)

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

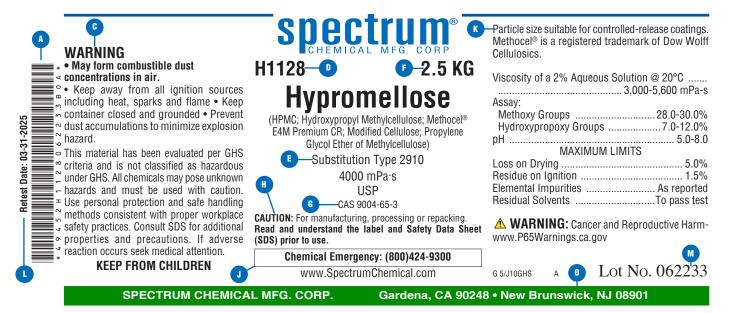
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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.



- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Storage Color Band

- Size/Quantity
- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical Emergency Telephone Number
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

# YELLOW: Oxidizer RED: Flammable GREEN: General Storage BLUE: Health Hazard WHITE: Corrosive

#### Spectrum Chemical Mfg Corp

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