



# Scientific Documentation

H1128, Hypromellose, Substitution Type 2910,  
4000 mPa.s, 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

Ver4.06 17.September.2021

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

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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          | HPMC ; Hydroxypropyl Methylcellulose ; Methocel E4M Premium CR ; Modified Cellulose ; |

| 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:**  
769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**  
14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000

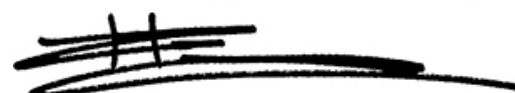
|                   |   |                  |         |
|-------------------|---|------------------|---------|
| Item Number       | H1128   | Lot Number       | 2KC0259 |
| Item              | Hypromellose, Substitution Type 2910, 4000 mPa.s, USP |                  |         |
| CAS Number        | 9004-65-3   |                  |         |
| Molecular Formula |   | Molecular Weight |         |

| Test  | Specification |             | Result                   |
|---|---------------|-------------|--------------------------|
|   | min           | max         |                          |
| VISCOSITY OF A 2% AQUEOUS SOLUTION @ 20D °C | 3,000         | 5,600 mPa·s | 3833                     |
| ASSAY (METHOXY GROUPS)                      | 28.0          | 30.0%       | 28.8                     |
| ASSAY:HYDROXYPROPOXY GROUPS                 | 7.0           | 12.0%       | 9.5 %                    |
| pH  | 5.0           | 8.0         | 6.2                      |
| LOSS ON DRYING                              |               | 5.0%        | 2.6 %                    |
| RESIDUE ON IGNITION                         |               | 1.5%        | 0.2 %                    |
| ELEMENTAL IMPURITIES:                       |               |             | .                        |
| NICKEL (Ni)                                 | AS REPORTED   |             | 1.1 PPM                  |
| CHROMIUM (Cr)                               | AS REPORTED   |             | 0.28 PPM                 |
| IDENTIFICATION                              | TO PASS TEST  |             | PASSES TEST              |
| RETEST DATE                                 |               |             | 12-SEP-2025              |
| MANUFACTURE DATE                            |               |             | 13-SEP-2020              |
| APPEARANCE                                  |               |             | WHITE POWDER             |
| RESIDUAL SOLVENTS                           | TO PASS TEST  |             | NO RESIDUAL SOLVENT USED |

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Certified by:



Himanshu Patel  
Quality Control Manager  
Spectrum Chemicals & Laboratory Products

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

Preparation Date: 8/27/2014

Revision Date: 9/7/2018

Revision Number: G2

### 1. IDENTIFICATION

**Product identifier**

**Product code:** H1128  
**Product Name:** HYPROMELLOSE 2910, 4000 CPS, CR, USP

**Other means of identification**

**Synonyms:** Hydroxypropyl Methylcellulose; Propylene Glycol Ether of Methylcellulose; Modified Cellulose; HPMC; Hypromellose Substitution type 2910 4000 mPa s  
**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 | - |
|------------------|---|

**Label elements**

**Warning**  
 May form combustible dust concentrations in air

**Hazards not otherwise classified (HNOC)**  
 Not Applicable

**Other hazards**  
 Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Components                  | CAS-No.   | Weight % |
|-----------------------------|-----------|----------|
| Hypromellose 2910, 4000 cps | 9004-65-3 | 100      |

### 4. FIRST AID MEASURES

#### First aid measures

|                        |   |
|------------------------|---|
| <b>General Advice:</b> | 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. |
| <b>Skin Contact:</b>   | Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.                          |
| <b>Eye Contact:</b>    | Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.  |
| <b>Inhalation:</b>     | Move to fresh air. If breathing is difficult, give oxygen. In case of shortness of breath, give oxygen. Get medical attention.  |
| <b>Ingestion:</b>      | 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

#### Indication of any immediate medical attention and special treatment needed

**Notes to Physician:** Treat symptomatically.

#### 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 (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

#### Specific hazards arising from the chemical

**Hazardous Combustion Products:** Carbon Monoxide, Carbon Dioxide.

**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.

#### Special Protective Actions for Firefighters

**Product code:** H1128

**Product name:** HYPROMELLOSE  
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**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** No information available.

### 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. Avoid creating dust. 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 vapors/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**

##### **United States**

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| Components                  | CAS-No.   | OSHA | NIOSH | ACGIH | AIHA WEEL |
|-----------------------------|-----------|------|-------|-------|-----------|
| Hypromellose 2910, 4000 cps | 9004-65-3 | None | None  | None  | None      |

### Canada

| Components                  | CAS-No.   | Canada - Alberta | Canada - British Columbia | Canada - Ontario | Canada - Quebec |
|-----------------------------|-----------|------------------|---------------------------|------------------|-----------------|
| Hypromellose 2910, 4000 cps | 9004-65-3 | None             | None                      | None             | None            |

### Australia and Mexico

| Components                  | CAS-No.   | Australia | Mexico |
|-----------------------------|-----------|-----------|--------|
| Hypromellose 2910, 4000 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 Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing  
Chemical resistant apron  
Gloves
- Respiratory protection:** Wear respirator with dust filter.
- 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):

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**Product name:** HYPROMELLOSE  
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No information available

**Flash Point Tested according to:**  
Not available

**Upper Explosion Limit (%):**  
No information available

**Boiling point/range(°C/°F):**  
No information available

**Specific gravity:**  
No information available

**Evaporation rate:**  
No information available

**Odor threshold (ppm):**  
No information available

**Miscibility:**  
No information available

**Flammability:**  
No information available

**Autoignition Temperature (°C/°F):**  
No information available

**Melting point/range(°C/°F):**  
No information available

**Bulk density:**  
No information available

**pH:**  
No information available

**Vapor density:**  
No information available

**Partition coefficient  
(n-octanol/water):**  
No information available

**Solubility:**  
Soluble in Water

**Flashpoint (°C/°F):**  
No information available.

**Lower Explosion Limit (%):**  
No information available

**Decomposition temperature(°C/°F):**  
No information available

**Density (g/cm3):**  
No information available

**Vapor pressure @ 20°C (kPa):**  
No information available

**VOC content (g/L):**  
No information available

**Viscosity:**  
No information available

## 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:**

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**Product name:** HYPROMELLOSE  
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Ingestion. Inhalation.

## **Acute Toxicity**

### **Component Information**

|                             |           |
|-----------------------------|-----------|
| Hypromellose 2910, 4000 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** May cause hypermotility, diarrhea. Not expected to be a health hazard.  
**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 2910, 4000 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.

**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 2910, 4000 cps | 9004-65-3 | None                   | None                   | None                   | None                   |

## 14. TRANSPORT INFORMATION

### DOT

|  |                          |
|--|--------------------------|
| <b>UN-No:</b>                          | Not Regulated            |
| <b>Proper Shipping Name:</b>           | No information available |
| <b>Hazard Class:</b>                   | No information available |
| <b>Subsidiary Class</b>                | No information available |
| <b>Packing group:</b>                  | No information available |
| <b>Emergency Response Guide Number</b> | No information available |
| <b>Marine Pollutant</b>                | No data available        |
| <b>DOT RQ (lbs):</b>                   | No information available |
| <b>Special Provisions</b>              | No Information available |
| <b>Symbol(s):</b>                      | No information available |
| <b>Description:</b>                    | No information available |

### TDG (Canada)

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>Marine Pollutant</b>      | No Information available |
| <b>Description:</b>          | No information available |

### ADR

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>Subsidiary Risk:</b>      | No information available |

### IMO / IMDG

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |
| <b>Marine Pollutant</b>      | No information available |

### RID

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |

### ICAO

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |
| <b>Subsidiary Risk:</b>      | No information available |
| <b>Packing Group:</b>        | No information available |

### IATA

|                              |                          |
|------------------------------|--------------------------|
| <b>UN-No:</b>                | Not Regulated            |
| <b>Proper Shipping Name:</b> | No information available |
| <b>Hazard Class:</b>         | No information available |

**Product code:** H1128

**Product name:** HYPROMELLOSE  
2910, 4000 CPS, CR, USP

**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 2910, 4000 cps</i> | 9004-65-3 | PresentACTIVE | Present KE-05368 | Present             | Present (8)-196 | Present | Present          | Not present |

**U.S. Regulations**

*Hypromellose 2910, 4000 cps*

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

**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 2910, 4000 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 2910, 4000 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 2910, 4000 cps</i> | 9004-65-3 | Not Applicable  | Not Applicable                         |

**Canada**

**WHMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Component  
*Hypromellose 2910, 4000 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 2910, 4000 cps | 9004-65-3 | Present      | Not Listed    |

| Components                  | CAS-No.   | CEPA Schedule I - Toxic Substances                          |
|-----------------------------|-----------|---|
| Hypromellose 2910, 4000 cps | 9004-65-3 | Not listed  |
| Components                  | CAS-No.   | CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting |
| Hypromellose 2910, 4000 cps | 9004-65-3 | Not listed  |

### EU Classification

#### EU GHS - SV - CLP 1272/2008

| Components                  | CAS-No.   | EU GHS - SV - CLP (1272/2008) |
|-----------------------------|-----------|-------------------------------|
| Hypromellose 2910, 4000 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 2910, 4000 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:** 8/27/2014  
**Revision Date:** 9/7/2018  
**Prepared by:** Sonia Owen

#### 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  |
|----------------|---|
| 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 [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist



## 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 [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

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 [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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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** **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.

**L** Retest Date: 03-31-2025

**C** **KEEP FROM CHILDREN**

**spectrum®**  
CHEMICAL MFG CORP

**H1128** **D** **F** **2.5 KG**

**Hypromellose**

(HPMC; Hydroxypropyl Methylcellulose; Methocel® E4M Premium CR; Modified Cellulose; Propylene Glycol Ether of Methylcellulose)

**E** Substitution Type 2910  
4000 mPa·s  
USP

**H** **G** 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**

**J** [www.SpectrumChemical.com](http://www.SpectrumChemical.com)

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

Viscosity of a 2% Aqueous Solution @ 20°C ..... 3,000-5,600 mPa·s

Assay:

Methoxy Groups ..... 28.0-30.0%

Hydroxypropoxy Groups ..... 7.0-12.0%

pH ..... 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](http://www.P65Warnings.ca.gov)

**M** Lot No. 062233

G 5/J10GHS A **O**

**SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901**

- |   |  |  |
|---|--|--|
| <ul style="list-style-type: none"> <li><b>A</b> Bar Code</li> <li><b>B</b> GHS Hazard Pictograms</li> <li><b>C</b> Warning, Safety Data and Precautionary Information</li> <li><b>D</b> Product Catalog Number</li> <li><b>E</b> Item Name, Form, Grade</li> <li><b>O</b> Storage Color Band</li> </ul> | <ul style="list-style-type: none"> <li><b>F</b> Size/Quantity</li> <li><b>G</b> Chemical Abstracts Service (CAS) Registry Number</li> <li><b>H</b> Caution Information</li> <li><b>I</b> DOT Shipping Information</li> <li><b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number</li> </ul> | <ul style="list-style-type: none"> <li><b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel</li> <li><b>L</b> Expiration Information</li> <li><b>M</b> Lot Number</li> <li><b>N</b> Kosher Certified by Kosher Supervision of America (KSA).</li> </ul> |
|---|--|--|

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

**Corporate Headquarters:**  
769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**  
14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000



**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example:** ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example:** 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at [quality\\_assurance@spectrumchemical.com](mailto:quality_assurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

Oralia Chavez,  
Quality Assurance Specialist

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