

# Scientific Documentation

## Hydroxyethyl Cellulose, 5,000 cP, NF

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



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## Specification for Hydroxyethyl Cellulose, 5,000 cP, NF (H1236)

Item Number	H1236
Item	Hydroxyethyl Cellulose, 5,000 cP, NF
CAS Number	9004-62-0
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Cellulose 2-Hydroxyethyl Ether ; Hyetellose ; HEC

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (HYDROXYETHOXY GROUPS, DRIED BASIS)	30.0	70.0%
VISCOSITY OF 1% AQUEOUS SOLUTION @25°C	2500	7500 cP
pH (1%)	5.5	8.5
LOSS ON DRYING		10.0%
CHLORIDES		1.0 %
NITRATES (DRIED BASIS)		0.2 %
ALDEHYDES (as GLYOXAL)		20 ppm
RESIDUE ON IGNITION		1.0%
LEAD (Pb)		10 µg/g
ELEMENTAL IMPURITIES:		
ARSENIC	AS REPORTED	
MERCURY	AS REPORTED	
COPPER	AS REPORTED	
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	THE SOLUTION REMAINS CLEAR	
RETEST DATE		
DATE OF MANUFACTURE		

Test	Specification	
	Min	Max
MONOGRAPH EDITION		
RESIDUAL SOLVENTS:	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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<i><b>Corporate Headquarters:</b></i>	<i><b>West Coast Facility:</b></i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	H1236	Lot Number	1MI0274
Item	Hydroxyethyl Cellulose, 5,000 cP, NF	CAS Number	9004-62-0

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			OFF-WHITE POWDER
ASSAY (HYDROXYETHOXY GROUPS, DRIED BASIS)	30.0	70.0%	55.9 %
VISCOSITY OF 1% AQUEOUS SOLUTION @25°C	2500	7500 cP	2850 cP
pH (1%)	5.5	8.5	7.2
LOSS ON DRYING		10.0%	2.4 %
CHLORIDES		1.0 %	<0.2 %
NITRATES (DRIED BASIS)		0.2 %	0.1 %
ALDEHYDES (as GLYOXAL)		20 ppm	0.8 ppm
RESIDUE ON IGNITION		1.0%	0.6 %
LEAD (Pb)		10 µg/g	<0.5 µg/g
ELEMENTAL IMPURITIES:			.
ARSENIC	AS REPORTED		<0.4 µg/g
MERCURY	AS REPORTED		<0.5 µg/g
COPPER	AS REPORTED		<0.6 µg/g
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	THE SOLUTION REMAINS CLEAR		SOLUTION REMAINS CLEAR
RETEST DATE			11-OCT-2024
DATE OF MANUFACTURE			11-OCT-2022
MONOGRAPH EDITION			(USP-NF) 2023
RESIDUAL SOLVENTS:	AS REPORTED		.
CLASS 3 (solvent) / ACETONE			<5000 ppm

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm
OTHER RESIDUAL SOLVENTS: TERTIARY-BUTYL ALCOHOL			<350 ppm

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
16-OCT-23 08:57:47

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



Certificate of Analysis Results Approved By:

SHANSEN  
Selin Hansen  
16-OCT-23 16:36:48

**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: 3/25/2014

Revision date 11/26/2018

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** H1236  
**Product Name:** HYDROXYETHYL CELLULOSE, 5,000 CPS, NF

#### Other means of identification

**Synonyms:** Cellulose 2-Hydroxyethyl Ether  
2-Hydroxyethyl cellulose  
Hydroxyethyl cellulose ether  
2-Hydroxyethyl cellulose ether  
Hydroxyethyl ether cellulose  
Cellulose hydroxyethylate  
Cellosize  
Natrosol

**CAS #:** 9004-62-0  
**RTECS #** FJ5958000  
**CI#:** Not available

#### Recommended use of the chemical and restrictions on use

**Recommended use:** Thickening agent.  
**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 by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Combustible dust	-
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#### Label elements

##### Warning

May form combustible dust concentrations in air

**Product code:** H1236

**Product name:** HYDROXYETHYL  
CELLULOSE, 5,000 CPS, NF

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**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical name	CAS No.	Weight-%
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	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 (CO2). 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**

**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. 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

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **Control parameters**

**Product code:** H1236

**Product name:** HYDROXYETHYL  
CELLULOSE, 5,000 CPS, NF

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## National occupational exposure limits

### United States

Chemical name	CAS No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	None	None	None	None

### Canada

Chemical name	CAS No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	None	None	None	None

### Australia and Mexico

Chemical name	CAS No.	Australia	Mexico
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	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

<b>Eye protection:</b>	Safety glasses Safety glasses with side-shields.
<b>Skin and body protection:</b>	Long sleeved clothing Chemical resistant apron Gloves
<b>Respiratory protection:</b>	Wear respirator with dust filter.
<b>Hygiene measures:</b>	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

<b>Physical state:</b> Solid	<b>Appearance:</b> Powder.	<b>Color:</b> White. Off-white.
<b>Odor:</b> Odorless.	<b>Taste</b> Tasteless.	<b>Chemical name</b> No information available
<b>Molecular/Formula weight (g/mole):</b> No information available	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> No information available	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Soluble in Water	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### 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

**Hazardous decomposition products:** Carbon monoxide. Carbon dioxide.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

## Information on likely routes of exposure

### **Principal Routes of Exposure:**

Ingestion. Inhalation.

## Acute Toxicity

### **Component Information**

Hydroxyethyl Cellulose, 5000 cps	
CAS No.	9004-62-0

**LD50/oral/rat** = No information available

**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** No information available

**LD50/oral/mouse =**

**Value - Acute Tox Oral** = No information available

**LD50/dermal/rabbit**

**Value** No information available

**LD50/dermal/rat**

**VALUE -Acute Tox Dermal** = No information available

**LC50/inhalation/rat**

**VALUE-Gas** = 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** No information available. Health injuries are not known or expected under normal use. 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.

Chemical name	CAS No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	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 in soil** 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

Chemical name	CAS No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	None	None	None	None

#### 14. TRANSPORT INFORMATION

##### DOT

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

##### TDG (Canada)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

##### ADR

**UN Number** -  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Packing group** No information available  
**Subsidiary Risk:** No information available

##### IMDG

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

##### RID

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available

##### ICAO (air)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class** No information available  
**Subsidiary Risk:** No information available

**Packing Group:** No information available

**IATA**

**UN Number** Not Regulated  
**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** IF exposed or concerned

**15. REGULATORY INFORMATION**

**International Inventories**

Chemical name	CAS No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	IECSC	AICS	EINECS-No.
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	PresentACTIVE	PresentKE-20506	Present	Present(8)-194	Present	Present	Not present

**U.S. Regulations**

**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)

Chemical name	CAS No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Chemical name	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
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	None	None	None	None	None

**U.S. TSCA**

Chemical name	CAS No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	Not Applicable	Not Applicable

**Canada**

**WHIMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

**Product code:** H1236

**Product name:** HYDROXYETHYL  
CELLULOSE, 5,000 CPS, NF

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Component  
Hydroxyethyl Cellulose, 5000 cps  
9004-62-0 ( 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

#### DSL/NDSL

Chemical name	CAS No.	Canada (DSL)	Canada (NDSL)
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	Present	Not Listed

Chemical name	CAS No.	CEPA Schedule I - Toxic Substances
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	Not listed
Chemical name	CAS No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	Not listed

#### EU Classification

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

Chemical name	CAS No.	EU GHS - SV - CLP (1272/2008)
Hydroxyethyl Cellulose, 5000 cps	9004-62-0	

##### EU - CLP (1272/2008)

#### R-phrases(s)

not determined (not applicable)

#### S -phrase(s)

none

Chemical name	CAS No.	Classification	Concentration Limits:	Safety Phrases
Hydroxyethyl Cellulose, 5000 cps	9004-62-0		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: 3/25/2014  
Revision date 11/26/2018  
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

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CELLULOSE, 5,000 CPS, NF

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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
H1236	Hydroxyethyl Cellulose, 5,000 cP, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

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

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## **H1236, Hydroxyethyl Cellulose, 5,000 cP, NF**

### **Source Statement**

The above mentioned catalog item is manufactured from plant derived material (wood pulp and/or cotton linters). No animal derived products are used in the manufacturing process.

### **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### **GMO Statement**

The above mentioned catalog item may be manufactured with the use of genetically modified organisms. It is derived from wood pulp and/or cotton linters. While wood pulp starting material is not sourced from genetically modified organisms, cotton linters starting material may be produced from GMOs.

## **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using irradiation or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 24 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

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



**RE: Elemental Impurities - Hydroxyethyl Cellulose, 5,000 cP, NF (Cat# H1236)**

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
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 0.4 ppm
Mercury	Hg	1	< 0.5 ppm
Copper	Cu	3	< 0.6 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 - Hydroxyethyl Cellulose, 5,000 cP, NF (Cat# H1236)**

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Tertiary Butyl Alcohol	2	< 350 ppm
Acetone	3	< 5000 ppm
2-Propanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

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).

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## Label Information

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

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

This material has been evaluated per GHS criteria and is not classified as hazardous under GHS. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN**

**H1236** **SIZ SY**  
**Hydroxyethyl**  
**Cellulose**  
 (Cellulose 2-Hydroxyethyl Ether)  
 5,000 cP  
 N.F  
 CAS 9004-62-0

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

Assay (Hydroxyethoxy Groups, Dried Basis).....	30.0-70.0%
Viscosity of a 1% Solution.....	2500-7500 cP
pH (1 in 100).....	5.5-8.5
<b>MAXIMUM LIMITS</b>	
Loss on Drying.....	10.0%
Chlorides.....	1.0%
Nitrates (Dried Basis).....	0.2%
Aldehydes (as Glyoxal).....	20 ppm
Residue on Ignition.....	1.0%
Lead (Pb).....	10 µg/g
Elemental Impurities.....	As reported
Residual Solvents.....	To pass test

Keep tightly closed.

**WARNING:** Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

G 9/J10GHS

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Lot No. XQ####

### 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