

Scientific Documentation

Hydroxypropyl Cellulose, 75-150 cP, NF

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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Product Specification Certificate of Analysis Safety Data Sheet (SDS) Certification of Current Good Manufacturing Practices (cGMP) Technical Statements Elemental Impurities Statement Residual Solvents Statement General Label Information – Sample Label



Specification for Hydroxypropyl Cellulose, 75-150 cP, NF (HY117)

Item Number	HY117
Item	Hydroxypropyl Cellulose, 75-150 cP, NF
CAS Number	9004-64-2
Molecular Formula	
Molecular Weight	M.W. 95,000
MDL Number	
Synonyms	Cellulose, 2-Hydroxypropyl Ether ; Hyprolose

Test	Specificati	on
	Min	Max
ASSAY (HYDROXYPROPOXY GROUPS)	53.4	80.5 %
ROTATIONAL VISCOSITY OF A 5% AQUEOUS SOLN. @ 25°C	AS REPORTED	
pH OF A 1% SOLUTION	5.0 - 8.0	
LOSS ON DRYING		5.0 %
SILICA		0.6 %
RESIDUE ON IGNITION		0.8 %
LEAD		10 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

Spectrum Chemical Mfg Corp

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



Certificate Of Analysis

Item Number	HY117	Lot Number	2MA0078
Item	Hydroxypropyl Cellulose, 75-150 cP, NF	CAS Number	9004-64-2
Molecular Weight	M.W. 95,000		

TECT	SPECIFICATION		RESULT
TEST	MIN	MAX	RESULI
ASSAY (HYDROXYPROPOXY GROUPS)	53.4	80.5 %	73.7 %
ROTATIONAL VISCOSITY OF A 5% AQUEOUS SOLN. @ 25°C	AS REPORTED		92 cps
pH OF A 1% SOLUTION	5.0 - 8.0		5.4
LOSS ON DRYING		5.0 %	1.5 %
SILICA		0.6 %	<=0.6 %
RESIDUE ON IGNITION		0.8 %	0.2 %
LEAD		10 ppm	<2 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			20-DEC-2025
DATE OF MANUFACTURE			21-DEC-2022
APPEARANCE			FINE WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / HEPTANE			<5000 ppm
OTHER RESIDUAL SOLVENTS: TERT- BUTANOL			< 500 ppm

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 19-JAN-23 05:47:45

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



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.

Certificate of Analysis Results Approved By:

BPATEL Bhargavi Patel 19-JAN-23 07:46:02

SAFETY DATA SHEET spectrum®

Revision date 08-March-2021

HYDROXYPROPYL CELLULOSE, 75-100 CPS, NF
HY117
None
and restrictions on use
No information available
No information available
data sheet
Chemtrec 1-800-424-9300
Yes
NOC)

May form combustible dust concentrations in air

Appearance granules or powder

Physical state Solid

Odor No information available



Revision Number 2

Hazard statements

Other information No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Hydroxypropyl Cellulose, 75-100 cps	9004-64-2	100	*

*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 effe	cts, both acute and delayed
Symptoms	No information available.
Indication of any immediate medica	I attention and special treatment needed
Note to physicians	Treat symptomatically.
5. Fire-fighting measures	
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the 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.

U	•	e .
Specific hazards arising from the	Avoid generation of dust Fine	e dust dispersed in air may ignite.
	/ Wold gonoration of addt. I m	

Explosion data

chemical

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

Special protective equipment for Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. fire-fighters

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation. Avoid generation of dust. Avoid contact with eyes. Use personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharges.	
Other information	Refer to protective measures listed in Sections 7 and 8.	
Methods and material for containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so. Prevent dust cloud.	
Methods for cleaning up	Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. Pick up and transfer to properly labeled containers.	

-	11		
	Handlind	and storage	
		and Storade	

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure LimitsThe following ingredients are the only ingredients of the product above the cut-off level (or
level that contributes to the hazard classification of the mixture) which have an exposure
limit applicable in the region for which this safety data sheet is intended or other
recommended limit. At this time, the other relevant constituents have no known exposure
limits from the sources listed here.Appropriate engineering controlsShowers
Eyewash stations
Ventilation systems.Individual protection measures, such as personal protective equipmentWear safety glasses with side shields (or goggles).

Skin and body protection No special protective equipment required.

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Do not breathe dust.

9. Physical and chemical properties

Information on basic physical and chemical properties			
Physical state	Solid		
Appearance	granules or powder		
Color	White to Off-White		
Odor	No information available		
Odor threshold	No information available		
Property	Values	Remarks • Method	
pH	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			
Vapor pressure	No data available	None known	
Vapor density	no data available	None known	
Relative density	no data available	None known	
Water solubility	Slightly soluble in water	None known	
Solubility(ies)	no data available	None known	
Partition coefficient	No data available	None known	
Autoignition temperature	no data available	None known	
Decomposition temperature		None known	
Kinematic viscosity	no data available	None known	
Dynamic viscosity	No data available	None known	
Other information			
Explosive properties	No information available		
Oxidizing properties	No information available		
Softening point	No information available		
Molecular weight	95,000		
VOC Content (%)	No information available		
Liquid Density	No information available		
Bulk density	No information available		
10 Stability and reactivity			
10. Stability and reactivity			
Reactivity	No information available.		

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Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Excessive heat. Heating in air. dust formation.
Incompatible materials	None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

Information on likely routes of exposure

Product Information		
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.	
Eye contact	Specific test data for the substance or mixture is not available.	
Skin contact	Specific test data for the substance or mixture is not available.	
Ingestion	Specific test data for the substance or mixture is not available.	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	No information available.	

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Hydroxypropyl Cellulose,	= 10200 mg/kg (Rat)	-	-
75-100 cps			
9004-64-2			

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 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
<u>MEX</u>	not regulated
ICAO (air)	not regulated
IATA	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

<u>SARA 313</u>

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

<u>NFPA</u> Health hazards (Flammability 1 Instability 0 Physical and che <u>HMIS</u> Health hazards (Flammability 0 Physical hazards Personal protecti	mical properties -		
	abbreviations and acronyms used in the s B: EXPOSURE CONTROLS/PERSONAL Pf TWA (time-weighted average)		STEL (Short Term Exposure Limit)
Agency for Toxic S U.S. Environmenta European Food Sa EPA (Environment Acute Exposure G U.S. Environmenta	Maximum limit value erences and sources for data used to com Substances and Disease Registry (ATSDR) al Protection Agency ChemView Database afety Authority (EFSA) cal Protection Agency) uideline Level(s) (AEGL(s)) al Protection Agency Federal Insecticide, Fur al Protection Agency High Production Volume	ngicide, and Rodenti	icide Act
Food Research Jo Hazardous Substa International Unifo Japan GHS Classi Australia National NIOSH (National In National Library of National Library of National Toxicolog New Zealand's Ch Organization for E	urnal nce Database rm Chemical Information Database (IUCLID) fication Industrial Chemicals Notification and Assess nstitute for Occupational Safety and Health) Medicine's ChemID Plus (NLM CIP) Medicine's PubMed database (NLM PUBME) sment Scheme (NICI ED) ase (CCID) vironment, Health, a	nd Safety Publications

Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date Revision Note <u>Disclaimer</u> 08-March-2021 No information available.

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

spectrum

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
HY117	Hydroxypropyl Cellulose, 75-150 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: Spectrum-New Brunswick, NJ: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist

Spectrum[®] **HY117**, Hydroxypropyl Cellulose, 75-150 cP, NF

Source Statement

The above mentioned catalog item is manufactured from plant origin material (cellulose wood pulp). No animal derived products are used in the manufacturing process.

BSE/TSE Statement

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

Allergen Statement

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

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

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 is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

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



Nitrosamine Statement

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

Animal Testing Statement

The above mentioned catalog item may be tested on animals for regulatory compliance purposes.

Organic Compliance Statement

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

- Pesticides
- Phthalates
- Preservatives

spectrum®

RE: Elemental Impurities - Hydroxypropyl Cellulose, 75-150 cP, NF (Cat# HY117)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are 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 <u>TechServices@spectrumchemical.com.</u>

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

AN ISO 9001:2015 REGISTERED COMPANY

spectrum

RE: Residual Solvents - Hydroxypropyl Cellulose, 75-150 cP, NF (Cat# HY117)

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
Acetone	3	< 5000 ppm
Heptane	3	< 5000 ppm
Tertiarybutylalcohol		< 500 ppm

No Class 1, Class 2 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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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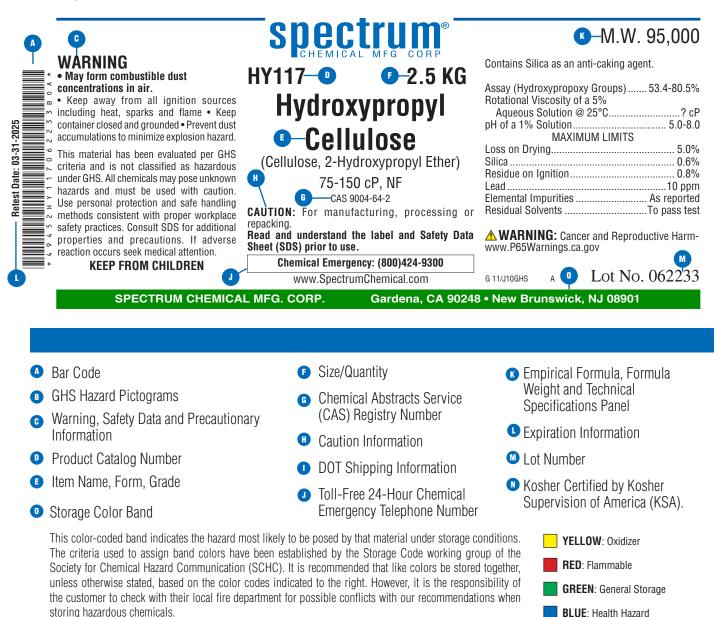
AN ISO 9001:2015 REGISTERED COMPANY

spectrum®

WHITE: Corrosive

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.



Spectrum Chemical Mfg Corp

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