

Scientific Documentation

Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





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Specification for Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP (CA192)

Item Number	CA192
Item	Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP
CAS Number	9004-32-4
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Sodium Carboxymethylcellulose ; Base H ; Carmellose Sodium ; Cellulose, Carboxymethyl Ether Sodium Salt

Test	Specification	1
	Min	Max
VISCOSITY OF 2% AQUEOUS SOLN. @25 C	400	800 cP
SODIUM (DRIED BASIS)	6.5	9.5 %
pH OF A 1 % SOLUTION @ 25°C	6.5	8.5
LOSS ON DRYING		10.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION:A	RED PURPLE COLOR DEVELOPS	
IDENTIFICATION (B)	FINE WHITE PRECIPITATE FORMS	
IDENTIFICATION (C)	POSITIVE FOR SODIUM	
CERTIFIED HALAL		
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

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

- 8	Item Number	CA192	Lot Number	1MK0202	
	tem	Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP	CAS Number	9004-32- 4	

TECT	SPECIF	CATION	DECULT
TEST	MIN	MAX	RESULT
VISCOSITY OF 2% AQUEOUS SOLN. @25 C	400	800 cP	445 cPs
SODIUM (DRIED BASIS)	6.5	9.5 %	8.29 %
pH OF A 1 % SOLUTION @ 25 ^o C	6.5	8.5	7.7
LOSS ON DRYING		10.0 %	7.2%
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION:A	RED PURPLE COLOR DEVELOPS		RED PURPLE COLOR DEVELOPS
IDENTIFICATION (B)	FINE WHITE PRECIPITATE FORMS		FINE WHITE PRECIPITATE FORMS
IDENTIFICATION (C)	POSITIVE FOR SODIUM		POSITIVE FOR SODIUM
CERTIFIED HALAL			CERTIFIED HALAL
RETEST DATE			01-AUG-2027
DATE OF MANUFACTURE			01-SEP-2023
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 19-DEC-23 15:52:41

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



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:

DGARCIA Dylan Garcia 19-DEC-23 15:57:52

SAFETY DATA SHEET

Revision date 14-April-2024

1. Identification	
Product identifier	
Product Name	CARBOXYMETHYLCELLULOSE SODIUM, MEDIUM VISCOSITY, VISCOSITY OF 2 PERCENT AQUEOUS SOLUTION @ 25 DEG C: 400-800 CPS, USP
Other means of identification	
Product Code(s)	CA192
Synonyms	None
Recommended use of the chemical and restrictions on use	
Recommended use	No information available
Restrictions on use	No information available
Details of the supplier of the safety	data sheet
Supplier Address Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000	
Emergency telephone number	

Emergency Telephone

Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

The product contains no substances which at their given concentration, are considered to be hazardous to health.



Revision Number 3

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Carboxymethylcellulose Sodium	9004-32-4	100

4. First-aid measures

Description of first aid measures Show this safety data sheet to the doctor in attendance. **General advice** Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep Eye contact eve wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area. Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. If symptoms persist, call a physician. Ingestion Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician. Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Wear personal protective clothing (see section 8). Avoid contact with skin, eyes or clothing. Most important symptoms and effects, both acute and delayed May cause redness and tearing of the eyes. Burning sensation. Symptoms Indication of any immediate medical 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.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.
Explosion data Sensitivity to mechanical impact none.	

Sensitivity to static discharge none.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	
Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.
Other information	Refer to protective measures listed in Sections 7 and 8.
Methods and material for containm	ent and cleaning up
Methods for containment	Prevent further leakage or spillage if safe to do so.

7. Handling and storage		
Precautions for safe handling		
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.	
Conditions for safe storage, includi	ing any incompatibilities	
Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.	

8. Exposure controls/personal protection

Control parameters

Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.
Appropriate engineering controls	
Engineering controls	Showers Eyewash stations Ventilation systems.
Individual protection measures, suc	ch as personal protective equipment
Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing.

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

Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

9. Physical and chemical properties

Information on basic physical and chemical properties

information on basic physical and o		
Physical state	Solid	
Appearance	powder or granules	
Color	White to Cream	
Odor	No information available	
Odor threshold	No information available	
Property	Values	Remarks • Method
рН	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	1.6	None known
Water solubility	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	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	
•		

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong acids. Strong bases. Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Symptoms related to the physical,	chemical and toxicological characteristics
Symptoms	Redness. May cause redness and tearing of the eyes.
Acute toxicity	
Numerical measures of toxicity	

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Carboxymethylcellulose Sodium	= 27000 mg/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
9004-32-4			

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

Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.	
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.	
Respiratory or skin sensitization	No information available.	
Germ cell mutagenicity	No information available.	
Carcinogenicity	No information available.	
Reproductive toxicity	No information available.	
STOT - single exposure	No information available.	
STOT - repeated exposure	No information available.	
Aspiration hazard	No information available.	
Other adverse effects	No information available.	
Interactive effects	No information available.	

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	

Carboxymethylcellulose Sodium 9004-32-4	- >20000 mg/l 96 h LC50 ONcorhynchus mykiss (Rainbow Trout) (Ecotox - U.S. EPA)	- 87.26 mg/l 48 h EC50 Ceriodaphnia dubia (Ecotox - U.S. EPA)	
Persistence and degradab	lity No information available.		
Bioaccumulation	Inherently biodegradable.	Inherently biodegradable.	
Other adverse effects	No information available.	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 ENCS	Does not Comply This product complies with ENCS:
IECSC	This product complies with Elines.
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

- **TSCA** United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA Health hazards 0 Flammability 0 Instability 0 Physical and chemical properties -<u>HMIS</u> Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheetLegendSection 8: EXPOSURE CONTROLS/PERSONAL PROTECTIONTWATWA (time-weighted average)STELSTELCeilingMaximum limit value

STEL (Short Term Exposure Limit)

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date	14-April-2024	
Revision Note	No information available.	
Disclaimer		

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

End of Safety Data Sheet

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
CA192	Carboxymethylcellulose Sodium, Medium Viscosity Viscosity of 2 % Aqueous Solution @ 25 DEG C: 400-800 cP, 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:2020632Spectrum-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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

Oulu Clamy

Oralia Chavez Quality Assurance Specialist

spectrum[®]

CA192, Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP

Source Statement

The above mentioned catalog item is manufactured from cellulose (soft wood trees). 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.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 12 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)

- Phthalates
- Preservatives

spectrum®

RE: Elemental Impurities - Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP (Cat# CA192)

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
Cadmium	Cd	1	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 2 ppm
Nickel	Ni	2A	< 3 ppm
Silver	Ag	2B	< 5 ppm
Antimony	Sb	3	< 1 ppm
Copper	Cu	3	< 1 ppm
Tin	Sn	3	< 5 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 <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



RE: Residual Solvents - Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP (Cat# CA192)

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
Methanol	2	< 3000 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 <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®

YELLOW: Oxidizer

RED: Flammable

GREEN: General Storage

BLUE: Health Hazard

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.



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.

Spectrum Chemical Mfg Corp

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

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