Scientific Documentation

CA192, Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 % 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

Ver4.06 18.November.2021

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

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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	Base H ; Carmellose Sodium ; Cellulose, Carboxymethyl Ether Sodium Salt ; Sodium

Test	Specification	
	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:
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

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

Certificate Of Analysis

Item Number	CA192	Lot Number	2KI0334
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	

Test	Specification		Result
	min	max	
VISCOSITY OF 2% AQUEOUS SOLN. @25 C	400	800 cP	691 cPs
SODIUM (DRIED BASIS)	6.5	9.5 %	8.4 %
pH OF A 1 % SOLUTION @ 25°C	6.5	8.5	7.1
LOSS ON DRYING		10.0 %	5.5 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION:A	RED PURPLE COLOR DEVELOPS		PURPLE COLOR DEVLOPS
IDENTIFICATION (B)	FINE WHITE PRECIPITATE FORMS		FINE WHITE PRECIPITATE FORMS
IDENTIFICATION (C)	POSITIVE FOR SODIUM		POSITIVE FOR SODIUM
CERTIFIED HALAL			CERTIFIED HALAL
RETEST DATE			03-MAY-2022
DATE OF MANUFACTURE			03-MAY-2021
APPEARANCE			TAN CRYSTALLINE POWDER
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:

Jigisha Patel
VP Regulatory Compliance & Technical Services, Regulatory

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: 1/22/2015 **Revision Date:** 6/13/2018 **Revision Number:** G3

1. IDENTIFICATION

Product identifier

Product code: CA192
Product Name: CARBOXYMETHYLCELLULOSE SODIUM, MEDIUM VISCOSITY, VISCOSITY OF 2 PERCENT AQUEOUS SOLUTION @ 25 DEG C: 400-800 CPS, USP

Other means of identification
Synonyms:
Carmellose Sodium
Cellulose, Carboxymethyl Ether, Sodium Salt
Sodium Carboxymethylcellulose
Carboxymethylcellulose, sodium salt
Cellulose sodium glycolate
Cellulose glycolic acid, sodium salt
Sodium CMC;
Sodium CM-cellulose;
Sodium celluose glycolate;
Sodium glycolate cellulose;
Sodium salt of carboxymethylcellulose
Aquaplast; Carmethose; Cellofas; Cellpro; CMC sodium salt; Collowel; Ethoxose; Lovosa; NaCm-cellulose salt; Tylose C

CAS #: 9004-32-4
RTECS # FJ5950000
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

Precautionary Statements - Prevention
Keep away from all ignition sources including heat, sparks, and flame
Keep container closed and grounded
Prevent dust accumulations to minimize explosion hazard

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Carboxymethylcellulose Sodium	9004-32-4	100

4. FIRST AID MEASURES

First aid measures

General Advice: 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.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. In case of shortness of breath, give oxygen. Get medical attention.

Ingestion: 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

Ingestion may cause gastrointestinal irritation, nausea, vomiting, and diarrhea

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_2). 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 Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system.

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. Use only non-sparking tools. 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

Components	CAS-No.	**OSHA**	**NIOSH**	**ACGIH**	**AIHA WEEL**
Carboxymethylcellulose Sodium	9004-32-4	None	None	None	None

Canada

Components	CAS-No.	**Canada - Alberta**	**Canada - British Columbia**	**Canada - Ontario**	**Canada - Quebec**
Carboxymethylcellulose Sodium	9004-32-4	None	None	None	None

Australia and Mexico

Components	CAS-No.	**Australia**	**Mexico**
Carboxymethylcellulose Sodium	9004-32-4	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:	Goggles Safety glasses with side-shields
Skin and body protection:	Long sleeved clothing Chemical resistant apron Gloves
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
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: No information available	**Flammability:** No information available	**Flashpoint (°C/°F):** No information available.
Flash Point Tested according to: Not available	**Autoignition Temperature (°C/°F):** 360-370 °C/680-698 °F	**Lower Explosion Limit (%):** No information available
Upper Explosion Limit (%): No information available	**Melting point/range(°C/°F):** No information available	**Decomposition temperature(°C/°F):** No information available
Boiling point/range(°C/°F): No information available	**Bulk density:** No information available	**Density (g/cm3):** 1.59
Specific gravity: No information available	**pH:** No information available	**Vapor pressure @ 20°C (kPa):** No information available

Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

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

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Soluble in Water

10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents
Reactive with acids
Reacts with strong bases

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:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Carboxymethylcellulose Sodium	
CAS-No.	9004-32-4

LD50/oral/rat = 27000 mg/kg
LD50/oral/mouse = >27000 mg/kg
LD50/dermal/rabbit = >2000 mg/kg
LD50/dermal/rat = =27000mg/kgOral LD50Rat >5800mg/m^{3}Inhalation LC50Rat
LC50/inhalation/rat = >5800 mg/m^3 Inhalation LC50 Rat 4 h
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = 16000 mg/kg Oral LD50 Guinea Pig >27000 mg/kg Oral LD50 Rabbit

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 27000 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = >27000

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = > 2000 mg/kg

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 = >5800 mg/m^3 (4-hr.)

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	Not expected to be a health hazard. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Aspiration hazard	No information available.

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

Chronic Toxicity	Prolonged or repeated ingestion may affect the liver, urinary system, and metabolism. Repeated exposure may cause bronchitis to develop with cough, phlegm, and /or shortness of breath.
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
Carboxymethylcellulose Sodium	9004-32-4	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: Aquatic environment.

Carboxymethylcellulose Sodium - 9004-32-4
Freshwater Fish Species Data: >20000 mg/l 96 h LC50 ONcorhynchus mykiss (Rainbow Trout) (Ecotox - U.S. EPA)
Water Flea Data: 87.26 mg/l 48 h EC50 Ceriodaphnia dubia (Ecotox - U.S. EPA)

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
Carboxymethylcellulose Sodium	9004-32-4	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-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Packing Group:	No information available
Subsidiary Risk:	No information available

IMO / 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-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available

Subsidiary Risk: No information available
Packing Group: No information available

ICAO
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-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
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.
Carboxymethylcellulose Sodium	9004-32-4	Present XU (ACTIVE)	Present KE-05354	Present	Present (8)-181 (8)-185 (8)-203	Present [33850]	Present	Not present

U.S. Regulations

Carboxymethylcellulose Sodium
FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 182.1745
FDA - Direct Food Additives 21 CFR 173.310
FDA - 21 CFR - Total Food Additives 133.178 133.179 150.141 150.161 173.310 175.105 182.1745

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:
Carboxymethylcellulose Sodium	9004-32-4	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
Carboxymethylcellul	9004-32-4	None	None	None	None	None

ose Sodium						

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**
Carboxymethylcellulose Sodium	9004-32-4	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: Not a dangerous product according to HPR classification criteria.

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

WHMIS 1988 Hazard Class
Non-controlled

Canada Controlled Products Regulation:
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Carboxymethylcellulose Sodium	9004-32-4	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Carboxymethylcellulose Sodium	9004-32-4	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Carboxymethylcellulose Sodium	9004-32-4	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Carboxymethylcellulose Sodium	9004-32-4	No information

EU - CLP (1272/2008)

R-phrase(s)
not determined (not applicable)

S -phrase(s)
none

Components	CAS-No.	**Classification**	**Concentration**	**Safety Phrases**

			Limits:	
Carboxymethylcellulose Sodium	9004-32-4		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: 1/22/2015
Revision Date: 6/13/2018
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

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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: 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

Sincerely,

Oralia Chavez
Quality Assurance Specialist

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

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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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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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

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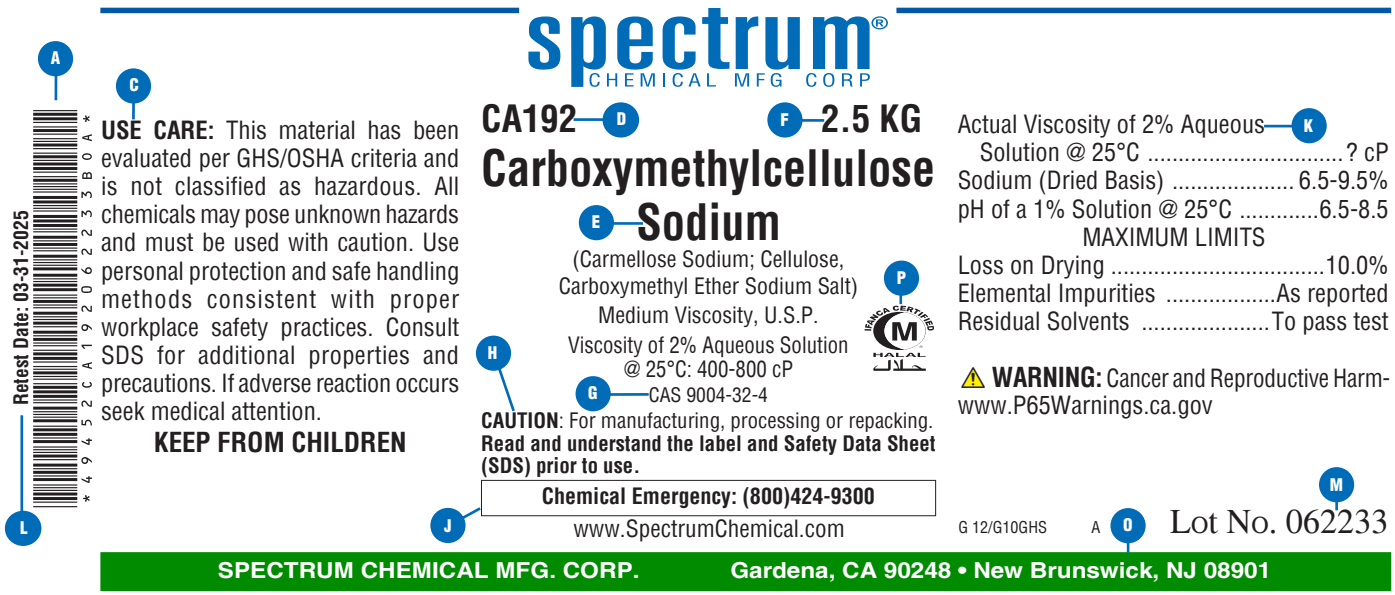
Label Information

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.



- **A** Bar Code
- **B** GHS Hazard Pictograms
- **C** Warning, Safety Data and Precautionary Information
- **D** Product Catalog Number
- **E** Item Name, Form, Grade
- **F** Size/Quantity
- **G** Chemical Abstracts Service (CAS) Registry Number
- **H** Caution Information
- **I** DOT Shipping Information
- **J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- **K** Empirical Formula, Formula Weight and Technical Specifications Panel
- **L** Expiration Information
- **M** Lot Number
- **N** Kosher Certified by Kosher Supervision of America (KSA).
- **O** Storage Color Band
- **P** Halal Certified by IFANCA
- **Q** bioCertified

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

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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 928th 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 706th 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 if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

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

المجلس الإسلامي الأمريكي للغذاء و التغذية

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA

IFANCA HALAL PRODUCT CERTIFICATE شهادة حلال

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: **November 02, 2021**

Document #: **11205.11206.II213973**

Company Name & Address: **Spectrum Laboratory Products, Inc.** 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA

Plant Name & Address: **Spectrum Laboratory Products, Inc.** 769-Jersey Ave New Brunswick, New Jersey 08901 USA

	ProductName	Product Code	Halal-ID	Product Certificate #
1.	Carboxymethylcellulose Sodium, Medium Viscosity, Viscosity of 2 Percent Aqueous Solution @ 25 DEG C: 400-800 cP, USP	CA192	B94087	HC-21SPHU72

Muhammad Munir Chaudry, Ph.D.
President

THE ISLAMIC FOOD AND NUTRITION COUNCIL OF AMERICA INCORPORATED ILLINOIS 1982

This Certificate is valid until **August 31, 2022** and subject to renewal at that time.

WORLD HALAL FOOD COUNCIL WHFC MEMBER

WWW.IFANCA.ORG • IFANCA Head Office • 777 Busse Highway • Park Ridge, Illinois 60068 USA • Tel: (847) 993-0034 • Fax (847) 993-0038

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