

# Scientific Documentation

## Microcrystalline Cellulose, 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 Microcrystalline Cellulose, NF (C1679)

Item Number	C1679
Item	Microcrystalline Cellulose, NF
CAS Number	9004-34-6
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Microcrystalline Cellulose ; Cellulose

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	VIOLET BLUE COLOR	
IDENTIFICATION (C)		350
pH OF SOLUTION	5.0	7.5
BULK DENSITY	0.20	0.30 g/cc
CONDUCTIVITY		75 $\mu$ S/cm
DEGREE OF POLYMERIZATION		350
LOSS ON DRYING		7.0 %
RESIDUE ON IGNITION		0.1 %
WATER-SOLUBLE SUBSTANCES		0.25 %
ETHER-SOLUBLE SUBSTANCES		0.05 %
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
MERCURY (Hg)	AS REPORTED	
COPPER (Cu)	AS REPORTED	
MICROBIAL LIMITS:		

Test	Specification	
	Min	Max
TOTAL AEROBIC MICROBIAL COUNT		1000 cfu/g
TOTAL COMBINED MOLDS & YEASTS COUNT		100 cfu/g
STAPHYLOCOCCUS AUREUS	ABSENT	
PSEUDOMONAS AERUGINOSA	ABSENT	
ESCHERICHIA COLI	ABSENT	
SALMONELLA	ABSENT	
CERTIFIED KOSHER		
RETEST DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		

***Spectrum Chemical Mfg Corp***

<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	C1679	Lot Number	2MK0009
Item	Microcrystalline Cellulose, NF	CAS Number	9004-34-6

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	VIOLET BLUE COLOR		VIOLET BLUE COLOR
IDENTIFICATION (C)		350	<350
pH OF SOLUTION	5.0	7.5	6.53
BULK DENSITY	0.20	0.30 g/cc	0.2715 g/cc
CONDUCTIVITY		75 µS/cm	46 µS/cm
DEGREE OF POLYMERIZATION		350	<350
LOSS ON DRYING		7.0 %	2.952 %
RESIDUE ON IGNITION		0.1 %	0.0294 %
WATER-SOLUBLE SUBSTANCES		0.25 %	0.1389 %
ETHER-SOLUBLE SUBSTANCES		0.05 %	0.0254 %
ELEMENTAL IMPURITIES:			.
CADMIUM (Cd)	AS REPORTED		<0.5 ppm
LEAD (Pb)	AS REPORTED		<1 ppm
ARSENIC (As)	AS REPORTED		<1 ppm
MERCURY (Hg)	AS REPORTED		<0.1 ppm
COPPER (Cu)	AS REPORTED		<0.25 ppm
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT		1000 cfu/g	<1000 cfu/g
TOTAL COMBINED MOLDS & YEASTS COUNT		100 cfu/g	<100 cfu/g
STAPHYLOCOCCUS AUREUS	ABSENT		ABSENT
PSEUDOMONAS AERUGINOSA	ABSENT		ABSENT

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ESCHERICHIA COLI	ABSENT		ABSENT
SALMONELLA	ABSENT		ABSENT
CERTIFIED KOSHER			CERTIFIED KOSHER
RETEST DATE			01-MAY-2028
DATE OF MANUFACTURE			01-JUN-2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENT PRESENT
MONOGRAPH EDITION			NF 2023

Certificate of Analysis Results Entered By:

CACEVEDO  
Charmian Acevedo  
16-APR-24 09:20:48

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
16-APR-24 09:25:05

**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

# spectrum®



Revision date 13-December-2023

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** MICROCRYSTALLINE CELLULOSE, NF

### Other means of identification

**Product Code(s)** C1679

**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

Combustible dust	Yes
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### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### **Hazard statements**

May form combustible dust concentrations in air

**Appearance** Powder

**Physical state** Solid

**Odor** Odorless

### **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

#### Unknown acute toxicity

#### Other information

No information available.

### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
Microcrystalline Cellulose	9004-34-6	100

### 4. First-aid measures

#### Description of first aid measures

<b>General advice</b>	Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a physician.
<b>Ingestion</b>	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.
<b>Self-protection of the first aider</b>	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).

#### Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	No information available.
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#### Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	Treat symptomatically.
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### 5. Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	Avoid generation of dust. Fine dust dispersed in air may ignite.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide.



**Explosion data****Sensitivity to mechanical impact** none.**Sensitivity to static discharge** yes.**Special protective equipment for fire-fighters**

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**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. Avoid contact with skin, eyes or clothing.

**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.

**7. Handling and storage****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. Avoid contact with skin, eyes or clothing.

**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 Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline Cellulose 9004-34-6	No data available	15 mg/m <sup>3</sup> TWA 5 mg/m <sup>3</sup> TWA	-

**Appropriate engineering controls****Engineering controls**Showers  
Eyewash stations  
Ventilation systems.**Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Hand protection</b>	Wear suitable gloves.
<b>Skin and body protection</b>	Wear suitable protective clothing. Long sleeved clothing.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Do not breathe dust. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder
<b>Color</b>	White
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	no data available	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	1.5	None known
<b>Water solubility</b>	Slightly soluble in water	None known
<b>Solubility(ies)</b>	no data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>	200 - °C / 392 °F	None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

### Other information

<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	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.

## 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.

**Skin contact** May be absorbed through the skin in harmful amounts. Harmful in contact with skin. (based on components).

**Ingestion** May be harmful if swallowed.

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

### Acute toxicity

#### Numerical measures of toxicity

#### Unknown acute toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Microcrystalline Cellulose 9004-34-6	> 5 g/kg ( Rat )	> 2000 mg/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h

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

**Skin corrosion/irritation** No information available.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitization** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.

**Reproductive toxicity** No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Target organ effects** respiratory system, Eyes, Skin.

**Aspiration hazard** No information available.

**Other adverse effects** No information available.

Interactive effects	No information available.
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## 12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

## 15. Regulatory information

### International Inventories

TSCA	Complies
------	----------

DSL/NDSL	Complies
EINECS/ELINCS	Complies
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/NDL** - 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 contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Microcrystalline Cellulose - 9004-34-6	carcinogen

**U.S. State Right-to-Know Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Microcrystalline Cellulose 9004-34-6	3227	Present	Present

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information****NFPA**

**Health hazards** 0

**Flammability** 1

**Instability** 0

**Physical and chemical properties** -

**HMIS**

**Health hazards** \*

Flammability 0  
Physical hazards 0  
Personal protection X  
*Chronic Hazard Star Legend*

*\* = Chronic Health Hazard*

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

**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

<b>Revision date</b>	13-December-2023
<b>Revision Note</b>	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**



**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
C1679	Microcrystalline Cellulose, 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)

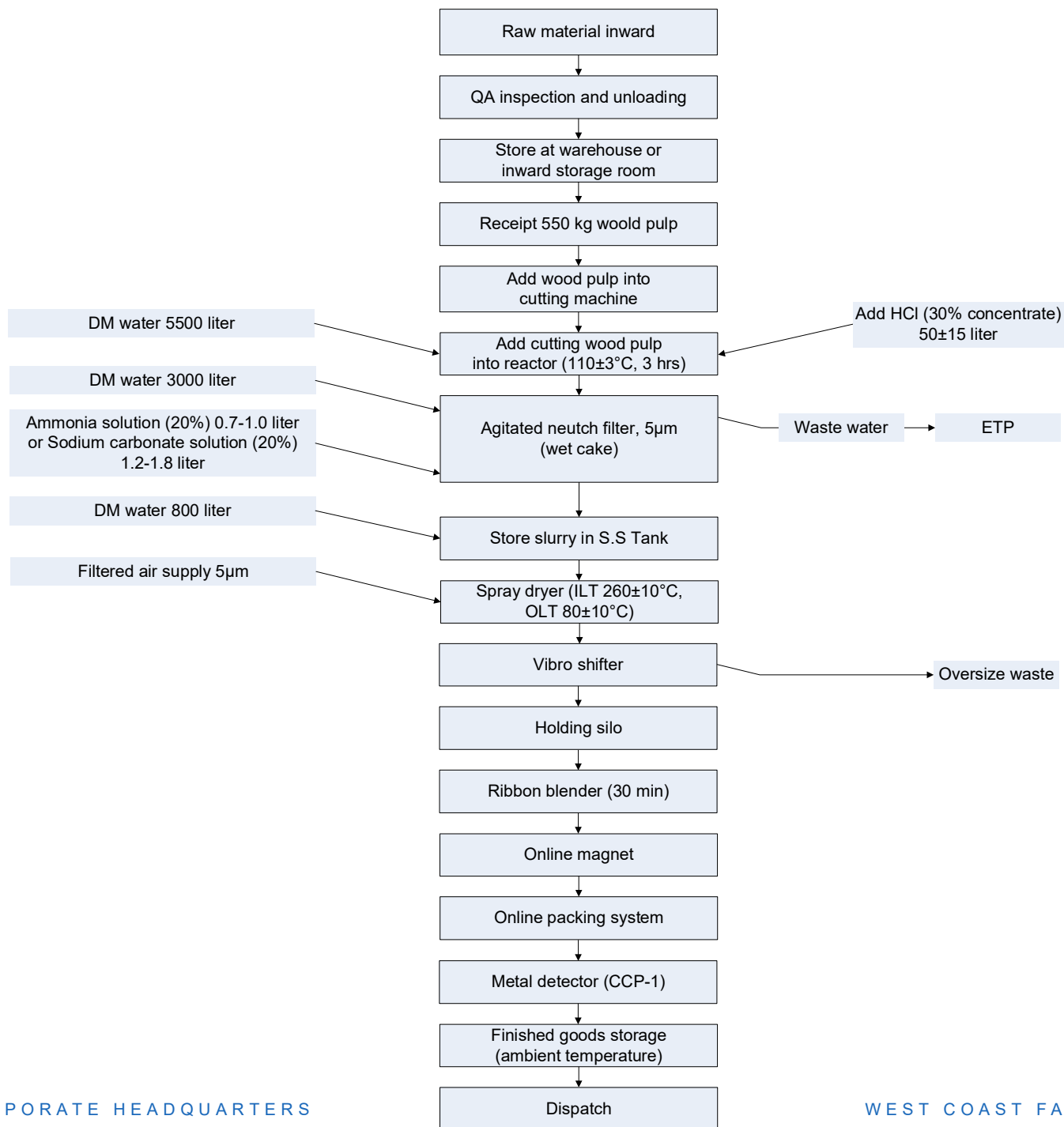
Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Microcrystalline Cellulose, NF - C1679



#### 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



## C1679, Microcrystalline Cellulose, NF

### Source Statement

The above mentioned catalog item is manufactured from plant origin material (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 has not been tested on animals.

## 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 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

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

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



**RE: Elemental Impurities - Microcrystalline Cellulose, NF (Cat# C1679)**

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	< 1 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 0.1 ppm
Copper	Cu	3	< 0.25 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**

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New Brunswick, NJ 08901

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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 - Microcrystalline Cellulose, NF (Cat# C1679)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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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.

**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**



**C1679** **2.5 KG**

**Microcrystalline Cellulose**

(Cellulose) NF

CAS 9004-34-6

**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

pH of Solution ..... 5.0-7.5

Bulk Density ..... 0.20-0.30 g/cc

**MAXIMUM LIMITS**

Conductivity ..... 75 µS/cm

Degree of Polymerization ..... 350

Loss on Drying ..... 7.0%

Residue on Ignition ..... 0.1%

Water-Soluble Substances ..... 0.25%

Ether-Soluble Substances ..... 0.05%

Elemental Impurities ..... As reported

Residual Solvents ..... To pass test

**Microbial Limits:**

Total Aerobic Microbial Count ..... 1,000 cfu/g

Total Combined Molds and Yeasts Count ..... 100 cfu/g

*Staphylococcus aureus* ..... To pass test

*Pseudomonas aeruginosa* ..... To pass test

*Escherichia coli* ..... To pass test

*Salmonella* ..... To pass test

**WARNING:** Cancer and Reproductive Harm-  
www.P65Warnings.ca.gov

G 9/J10GHS A **Lot No. 062233**

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

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

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



KOSHER SUPERVISION OF AMERICA

בס"ד  
Jan 18, 2024

The following product(s) prepared by the named company are certified kosher with the stated requirements:

**Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street,  
Gardena, CA 90248  
755-769 Jersey Ave.  
New Brunswick NJ 08901  
USA

**Product Name** C1679, Microcrystalline Cellulose, NF

**Brand** Spectrum

**UKD-ID** KSAV3-H5B4T76

**D/P/M** P

**Symbol Required** KSA

**Special Conditions**

This certificate expires on  
**Feb 01, 2025**

Rabbi Binyomin Lisbon  
Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.