

# Scientific Documentation

## Meclofenamate Sodium, USP

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



## **Table of Contents**

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

# Specification for Meclofenamate Sodium, USP (M1102)

Item Number	M1102
Item	Meclofenamate Sodium, USP
CAS Number	67254-91-5
Molecular Formula	$C_{14}H_{10}Cl_2NNaO_2 \cdot H_2O$
Molecular Weight	336.14
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY ( $C_{14}H_{10}Cl_2NNaO_2$ ; ANHYDROUS BASIS)	97.0	103.0 %
WATER DETERMINATION	4.8	5.8 %
COPPER		0.003 %
CHROMATOGRAPHIC PURITY	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

## *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
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	M1102	Lot Number	4KL0002
Item	Meclofenamate Sodium, USP	Manufacturer Lot	MEFNP01
CAS Number	67254-91-5	Manufacturer Code	13524
Molecular Formula	C <sub>14</sub> H <sub>10</sub> Cl <sub>2</sub> NNaO <sub>2</sub> •H <sub>2</sub> O	Molecular Weight	336.14

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (C <sub>14</sub> H <sub>10</sub> Cl <sub>2</sub> NNaO <sub>2</sub> ; ANHYDROUS BASIS)	97.0	103.0 %	98.9%
WATER DETERMINATION	4.8	5.8 %	4.9%
COPPER		0.003 %	<0.003%
CHROMATOGRAPHIC PURITY	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			30-MAR-2026
DATE OF MANUFACTURE			01-APR-2021
APPEARANCE			OFF WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			<3000 PPM
CLASS 2 (solvent) / TOLUENE			<890 PPM
CLASS 3 (solvent) / ACETONE			<3000 PPM
CLASS 3 (solvent) / 1-BUTANOL			<5000 PPM

Certificate of Analysis Results Entered By:

BPATEL  
Bhargavi Patel  
17-FEB-22 13:03:38

Certificate of Analysis Results Approved By:

BPATEL  
Bhargavi Patel  
17-FEB-22 13:03:55

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repackaging 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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Yung Shin Pharm. Ind. Co., Ltd. at 1191, Chung Shan Rd., Sec. 1, Tachia, Taichung City, 43744, Taiwan. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

# spectrum®



Revision date 19-October-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** MECLOFENAMATE SODIUM, USP

### Other means of identification

**Product Code(s)** M1102

**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

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2B
Skin sensitization	Category 1A
Specific target organ toxicity (single exposure)	Category 3

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### Hazard statements

Harmful if swallowed  
Causes eye irritation  
May cause an allergic skin reaction  
May cause respiratory irritation



**Appearance** Crystalline powder

**Physical state** Solid

**Odor** No information available

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Contaminated work clothing must not be allowed out of the workplace  
Wear protective gloves  
Use only outdoors or in a well-ventilated area

#### **Precautionary Statements - Response**

Specific treatment (see .? on this label)  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
If eye irritation persists: Get medical advice/attention  
IF ON SKIN: Wash with plenty of water and soap  
If skin irritation or rash occurs: Get medical advice/attention  
Wash contaminated clothing before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing  
Call a POISON CENTER or doctor if you feel unwell  
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell  
Rinse mouth

#### **Precautionary Statements - Storage**

Store in a well-ventilated place. Keep container tightly closed  
Store locked up.

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### **Other information**

No information available.

### **3. Composition/information on ingredients**

#### **Substance**

Chemical name	CAS No	Weight-%
Meclofenamate Sodium	6385-02-0	100

### **4. First-aid measures**

#### **Description of first aid measures**

##### **General advice**

Show this safety data sheet to the doctor in attendance.

##### **Inhalation**

Remove to fresh air. IF exposed or concerned: Get medical advice/attention.

##### **Eye contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists.  
Remove contact lenses, if present and easy to do. Continue rinsing.

##### **Skin contact**

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see 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.
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**Most important symptoms and effects, both acute and delayed**

Symptoms	Itching. Rashes. Hives.
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**Indication of any immediate medical attention and special treatment needed**

Note to physicians	May cause sensitization in susceptible persons. 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>	Product is or contains a sensitizer. May cause sensitization by skin contact.
<b>Hazardous combustion products</b>	Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Sodium oxides. Nitrogen oxides (NO <sub>x</sub> ). hydrogen chloride gas.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	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**

<b>Personal precautions</b>	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.

**Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## 7. Handling and storage

**Precautions for safe handling**

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.
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### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. 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, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields (or goggles). None required for consumer use.

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** 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.

## **9. Physical and chemical properties**

### Information on basic physical and chemical properties

**Physical state** Solid  
**Appearance** Crystalline powder  
**Color** White to Off-White  
**Odor** No information available  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	290 °C / 554 °F	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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in water	None known

<b>Solubility(ies)</b>	Soluble in Ethanol soluble in dimethylformamide Soluble in Dimethyl Sulfoxide	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b><u>Other information</u></b>		
<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.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	.
<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes eye irritation. May cause redness, itching, and pain.
<b>Skin contact</b>	May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components).
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

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

<b>Symptoms</b>	Itching. Rashes. Hives. May cause redness and tearing of the eyes.
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### Acute toxicity

**Numerical measures of toxicity**

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

<b>Skin corrosion/irritation</b>	May cause skin irritation.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Irritating to eyes.
<b>Respiratory or skin sensitization</b>	May cause sensitization by skin contact.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

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

## 15. Regulatory information

### International Inventories

**TSCA** Not listed

Note \*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

<b>DSL/NDSL</b>	Does not Comply
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product does not comply with china:
<b>KECL</b>	Complies
<b>PICCS</b>	Does not Comply
<b>AICS</b>	This product does not comply with 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** 2**Flammability** 0**Instability** 0**Physical and chemical properties** -**HMIS****Health hazards** 2**Flammability** 0**Physical hazards** 0**Personal protection** X**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

**Revision date**

19-October-2022

**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**

## 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
M1102	Meclofenamate Sodium, 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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,  
Quality Assurance  
Spectrum Chemical Mfg. Corp.

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

## Residual Solvents - Meclofenamate Sodium, USP (Catalog No. M1102)

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
Toluene	2	< 890 ppm
Acetone	3	< 3000 ppm
1-Butanol	3	< 5000 ppm

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

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

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

Sincerely,  
Technical Services  
Spectrum Chemical Mfg. Corp.

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

## Label Information


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

**WARNING**

- Harmful if swallowed • Causes eye irritation • May cause respiratory irritation • May cause an allergic skin reaction.
- Do not eat, drink or smoke when using this product
- Wear protective gloves • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling
- Contaminated work clothing must not be allowed out of the workplace.

**FIRST AID:** Call a POISON CENTER or physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**



**M1102**

**SIZ SY**

**Meclofenamate Sodium**

**USP**

CAS 67254-91-5

**C<sub>14</sub>H<sub>10</sub>Cl<sub>2</sub>NNaO<sub>2</sub>•H<sub>2</sub>O**

**F.W. 336.14**

Manufacturer/Supplier Code .....?

Manufacturer Lot Number .....?

Assay (C<sub>14</sub>H<sub>10</sub>Cl<sub>2</sub>NNaO<sub>2</sub>; Anhydrous Basis) ..... 97.0-103.0%

Water Determination ..... 4.8-5.8%

**MAXIMUM LIMITS**

Copper ..... 0.003%

Chromatographic Purity ..... To pass test

Elemental Impurities ..... As reported

Residual Solvents ..... To pass test

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

Lot No. XQ####

**Chemical Emergency: (800)424-9300**

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

### 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