



# Scientific Documentation

M1778, Meloxicam, 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

Ver4.03 5.December.2017



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA  
Director of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

**M1778, Meloxicam, USP**

## Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Certificate of Analysis Sample(s)
- General Label Information – Sample Label
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance
- Halal Certificate

**spectrum**<sup>®</sup>  
PHARMACEUTICAL MFG CORP



## Specification for Meloxicam, USP (M1778)

Item Number	M1778
Item	Meloxicam, USP
CAS Number	71125-38-7
Molecular Formula	C <sub>14</sub> H <sub>13</sub> N <sub>3</sub> O <sub>4</sub> S <sub>2</sub>
Molecular Weight	351.40
MDL Number	
Synonyms	4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide 1,1-

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
HEAVY METALS		10 ppm
ORGANIC IMPURITIES	TO PASS TEST	
IDENTIFICATION	TO PASS TEST	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

### *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

## SAFETY DATA SHEET

Preparation Date: 5/3/2016

Revision Date: 5/3/2016

Revision Number: G1

### 1. IDENTIFICATION

**Product identifier**

**Product code:** M1778  
**Product Name:** Meloxicam, USP

**Other means of identification**

**Synonyms:** Meloxicam  
**CAS #:** 71125-38-7  
**RTECS #** DL0702000  
**CI#:** Not available

**Recommended use of the chemical and restrictions on use**

**Recommended use:** Medication. Drug.  
**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)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3

**Label elements**

## Danger

### Hazard statements

Toxic if swallowed  
Causes skin irritation  
Causes serious eye irritation  
Suspected of damaging fertility or the unborn child  
May cause respiratory irritation



### Hazards not otherwise classified (HNOC)

Not Applicable

### Other hazards

Not available

### Precautionary Statements - Prevention

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Use personal protective equipment as required  
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  
Use only outdoors or in a well-ventilated area  
Wear protective gloves/protective clothing/eye protection/face protection

### Precautionary Statements - Response

*IF exposed or concerned: Get medical advice/attention*

*Specific treatment (see .? on this label)*

*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

If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

### Precautionary Statements - Storage

Store locked up

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

### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Meloxicam 71125-38-7	71125-38-7	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. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.

##### **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. If not breathing, give artificial respiration. Get medical attention.

##### **Ingestion:**

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

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

##### **Symptoms**

Irritating to eyes, respiratory system and skin. Ingestion may cause gastrointestinal irritation, nausea, vomiting, and diarrhea. Abdominal pain. Central nervous system effects. May affect the cardiovascular system. Hematuria (bloody urine). May affect the blood. It may affect the kidneys. May affect the liver. Jaundice. Chest tightness or pain. May affect eyes/vision. May cause bleeding or ulceration from the stomach.

#### **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:**

Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray mist or foam.

##### **Unsuitable Extinguishing Media:**

No information available.

#### **Specific hazards arising from the chemical**

##### **Hazardous Combustion Products:**

Carbon monoxide; Carbon dioxide; Nitrogen oxides; Sulfur oxides

##### **Specific hazards:**

May be combustible at high temperatures

#### **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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

### 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. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. 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. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

**Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. 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.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### National occupational exposure limits

U.S Occupational Exposure Limits: Not determined

**United States**

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Meloxicam 71125-38-7	None	None	None	None

**Canada**

Canada Occupational Exposure Limits: Not determined



Components	Alberta	British Columbia	Ontario	Quebec
Meloxicam 71125-38-7	None	None	None	None

### Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Meloxicam 71125-38-7	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.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

**Eye protection:** Goggles

**Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.

**Respiratory protection:** Effective dust mask. or. Wear respirator with dust filter.

**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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Powder.	<b>Color:</b> Light yellow.
<b>Odor:</b> None.	<b>Taste</b> No information available	<b>Formula:</b> No information available
<b>Molecular/Formula weight:</b> 351.40	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>pH:</b> No information available	<b>Melting point/range(°C/°F):</b> No information available
<b>Decomposition temperature(°C/°F):</b> No information available	<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available
<b>Density (g/cm<sup>3</sup>):</b> No information available	<b>Specific gravity:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Practically insoluble in water	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

**Stability:** Stable under recommended storage conditions

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Oxidizing agents.

**Hazardous decomposition products:** Carbon monoxide. Carbon dioxide. Nitrogen oxides (NO<sub>x</sub>). Sulfur oxides.

### 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

*Meloxicam - 71125-38-7*

**LD50/oral/rat** = 84 mg/kg

**LD50/oral/mouse** = 470 mg/kg

**LD50/dermal/rabbit** = No information available

**LD50/dermal/rat** = No information available

**LC50/inhalation/rat** = No information available

**LC50/inhalation/mouse** = No information available

**Other LD50 or LC50 information** = No information available

### Product Information

**LD50/oral/rat** =

**VALUE- Acute Tox Oral** = 84mg/kg

**LD50/oral/mouse** =

**Value - Acute Tox Oral** = 470mg/kg

**LD50/dermal/rabbit**

**VALUE-Acute Tox Dermal** = No information available

**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** = No information available

**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:** Contact with eyes may cause irritation.

**Inhalation** Irritating to respiratory system.

**Ingestion**

Toxic if swallowed. May cause upset stomach. May cause dehydration. May cause dry mouth, thirst. May cause bloating. May cause cholecystitis. May cause ulceration or bleeding from the stomach. May cause chest pain. It may affect cardiovascular system (hypertension). May affect the cardiovascular system (increased risk of heart attack or stroke). May affect the blood (agranulocytosis, leukopenia, increase risk of blood clots). May affect the blood (anemia). May affect urinary system (kidneys). Hematuria (blood in the urine). May cause painful or difficult urination. May affect the liver and cause jaundice, a yellowing of the skin and/or eyes. May affect behavior/central nervous system (convulsions). May affect behavior/central nervous system (ataxia). Health effects for nonsteroidal anti-inflammatory drugs (NSAIDs): nausea, vomiting, diarrhea, constipation, heartburn, stomach/abdominal pain, black or tarry stools, bleeding/bruising, swelling, sores/ulcers/white spots on lips and mouth, sweating, bluish colored skin, insomnia, mood/mental/personality changes, confusion, dizziness/drowsiness, headache, analgesia, itching, rash, weight gain/loss, vision and speech problems, ringing, tremors, difficulty breathing, increased heart rate or palpitations. Delayed effects may include gastrointestinal ulceration or bleeding, hypertension, kidney impairment, blood disorders, cardiovascular thrombotic events, stroke, congestive heart failure, fluid retention and edema, central nervous system effects (coma, convulsions, seizures, somnolence, analgesia, depression, anxiety, fatigue).

**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 gastrointestinal system. Prolonged or repeated ingestion may affect the liver, and kidneys. Prolonged or repeated ingestion may affect the cardiovascular system. Prolonged or repeated ingestion may cause ulceration or bleeding from the stomach. Prolonged or repeated ingestion may affect the blood (changes in clotting factors).

**Sensitization:**

No information available

**Mutagenic Effects:**

No information available

**Carcinogenic effects:**

Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Meloxicam	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

**Reproductive toxicity**

Suspected of damaging fertility or the unborn child

**Reproductive Effects:**

Experiments have shown reproductive toxicity effects on laboratory animals  
May cause adverse reproductive effects based on animal data

**Developmental Effects:**

May cause adverse developmental effects based on animal data

**Teratogenic Effects:**

No information available

**Specific Target Organ Toxicity****STOT - single exposure**

Respiratory system.

**STOT - repeated exposure**

No information available

**Target Organs:**

Gastrointestinal tract. Cardiovascular system. Central nervous system. Liver.  
Kidneys.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Ecotoxicity effects:** No data available.

**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	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Meloxicam	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** None  
**ERG No:** No information available  
**Marine Pollutant:** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions:** No Information available  
**Symbol(s):** 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

### 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

## 14. TRANSPORT INFORMATION

### 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	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Meloxicam	Not Listed	Not present	Not present	Not present	Not present	Not present	Not present

### U.S. Regulations

#### 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	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Meloxicam	Not Listed	Not Listed	Not Listed	Not Listed

### CERCLA/SARA

Components	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 <i>de minimis</i>
Meloxicam	None	None	None	None	None

#### U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Meloxicam	Not Applicable	Not Applicable

#### Canada

##### WHMIS hazard class:

D1B Toxic materials

##### Meloxicam

This chemical has not yet been classified, but it could possibly be classified as WHMIS hazard Class D1B- material causing immediate and serious toxic effects (TOXIC)

##### 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	Canada (DSL)	Canada (NDSL)
Meloxicam	Not Listed	Not Listed

Components	CEPA Schedule I - Toxic Substances
Meloxicam	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Meloxicam	Not listed

#### EU Classification

##### R-phrase(s)

R25 - Toxic if swallowed.

R36/37/38 - Irritating to eyes, respiratory system and skin.

##### S -phrase(s)

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	Classification	Concentration Limits:	Safety Phrases
Meloxicam		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

##### Indication of danger:

T - Toxic

Xi - Irritant.



## 16. OTHER INFORMATION

**Preparation Date:** 5/3/2016  
**Revision Date:** 5/3/2016  
**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**





## **Manufacturer**

Product Covered: M1778, Meloxicam, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA  
Director of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

# CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

## Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248,  
USA,

Additional sites: 13915 South Main Street, Los Angeles, California,  
90061, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the  
requirements of:

## ISO 9001:2015

The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine  
chemicals, solutions, equipment, supplies and products for the  
laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance,  
biotechnology, environmental and process industries.

**Certificate Number:**

94-316m-03

**Initial Certification Date:**

27 December 1994

**Certificate Issue Date:**

31 July 2017

**Certificate Expiry Date:**

28 January 2019



A handwritten signature in black ink, appearing to read 'Calin Moldovean', written over a horizontal line.

**Authorized Signature**

**Calin Moldovean**

President Business Assurance

Intertek Testing Services NA, Inc. dba Intertek  
900 Chelmsford Street, Lowell, MA, USA



# APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations by the management system of

## Spectrum Chemicals and Laboratory Products, Inc.

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.



# Certificate of Registration

# Intertek

This is to certify that the quality management system of

## Spectrum China Ltd.

**Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China**

has been assessed and registered by Intertek as conforming to the requirements of

## ISO 9001: 2008

The quality management system is applicable to:

*Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.*

Organization Code: 77762704-8  
Certificate Number: 111310001-01  
Certificate Issue Date: 17 November 2015  
Certificate Expiry Date: 14 September 2018



014

A handwritten signature in black ink, appearing to read "Calin Moldovean".

*Authorised Signature: Calin Moldovean – President, Business Assurance  
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom*  
Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.  
The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



The certificate remains the property of Intertek, to whom it must be returned upon request.

July 13, 2017

**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP and food grade products are 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.

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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum-Shanghai, China:	<u>3006174778</u>

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,



Oralia Chavez  
Quality Assurance Specialist

December 5, 2017

**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
M1778	Meloxicam, 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  
Spectrum-Shanghai, China: 03006174778

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,



Oralia Chavez  
Quality Assurance Specialist



Oct. 6, 2017

Re: Meloxicam, USP- M1778

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Meloxicam, USP- M1778

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfg. Corp.

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

Item Number	M1778	Lot Number	2FF0418
Item	Meloxicam, USP		
CAS Number	71125-38-7		
Molecular Formula	C <sub>14</sub> H <sub>13</sub> N <sub>3</sub> O <sub>4</sub> S <sub>2</sub>	Molecular Weight	351.40

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0	102.0 %	99.5 %
LOSS ON DRYING		0.5 %	0.18 %
RESIDUE ON IGNITION		0.1 %	0.02 %
HEAVY METALS		10 ppm	<10 ppm
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			31-MAR-2021
DATE OF MANUFACTURE			01-APR-2016
APPEARANCE			HIGHLIGHTER YELLOW CURDY POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 1 (solvent) / BENZENE			<2 ppm
CLASS 2 (solvent) / TETRAHYDROFURAN			<720 ppm
CLASS 2 (solvent) TOLUENE			<890 ppm
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ

Certificate Of Analysis Results Certified by



Ibad Tirmizi  
Director of Quality  
Spectrum Chemical Mfg. Corp.



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

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.



## 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** **DANGER**

- Toxic if swallowed • Causes serious eye irritation
- Causes skin irritation • May cause respiratory irritation • Suspected of damaging fertility or the unborn child.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Avoid breathing dust
- Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** Immediately call a POISON CENTER or physician. 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. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

**L** Exp. Date: 03-31-2025

**J** **KEEP FROM CHILDREN**



**M1778** **D** **F** **1 KG**

**E** **Meloxicam**  
[4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide]

**H** U.S.P.  
**G** CAS 71125-38-7

**H** **CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**  
[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

**K**  $C_{14}H_{13}N_3O_4S_2$  **F.W. 351.40**

Assay (Dried Basis) ..... 99.0-100.5%  
**MAXIMUM LIMITS**

Heavy Metals ..... 10 ppm  
Loss on Drying ..... 0.5%  
Residue on Ignition ..... 0.1%  
Organic Impurities ..... To pass test  
Residual Solvents ..... To pass test

**WARNING:** This product contains a chemical known to the State of California to cause cancer.

**WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. **M**

**B** 1/E5GHS **A** **O** 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

January 26, 2016

**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 928<sup>th</sup> 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

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 706<sup>th</sup> 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 [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,



Michael Dang  
Manager, GMP Compliance



## Stability – Shelf Life Guidance

Product Covered: M1778, Meloxicam, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, M1778, Meloxicam, USP, is assigned a 60 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez  
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters  
769 Jersey Avenue  
New Brunswick, NJ 08901-3605



# 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: September 05, 2017

Document #: 11205.11206.II170643

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

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

Product Name	Product Code	Halal-ID	Product Certificate #
Meloxicam, USP	M1778	C18414	HC-17SP1K64

  
Muhammad Munir Chaudry, Ph.D.  
President



This certificate is valid until **August 31, 2018** and subject to renewal at that time.

Page 1 of 1

