

# Scientific Documentation

## Metronidazole, 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)

## Specification for Metronidazole, USP (M1511)

Item Number	M1511
Item	Metronidazole, USP
CAS Number	443-48-1
Molecular Formula	C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>3</sub>
Molecular Weight	171.15
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	99.0	101.0%
LOSS ON DRYING		0.5%
ORGANIC IMPURITIES:		
TINIDAZOLE RELATED COMPOUND A		0.1 %
ANY SINGLE UNSPECIFIED IMPURITY		0.1 %
Total impurities		0.2 %
RESIDUE ON IGNITION		0.1 %
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	M1511	Lot Number	4HL0013
Item	Metronidazole, USP	Manufacturer Lot	RMTZP80224
CAS Number	443-48-1	Manufacturer Code	13524
Molecular Formula	C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>3</sub>	Molecular Weight	171.15

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	99.0	101.0%	100.4 %
LOSS ON DRYING		0.5%	0.16 %
ORGANIC IMPURITIES:			.
TINIDAZOLE RELATED COMPOUND A		0.1 %	0.01 %
ANY SINGLE UNSPECIFIED IMPURITY		0.1 %	0.01 %
Total impurities		0.2 %	0.04 %
RESIDUE ON IGNITION		0.1 %	0.04 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			31-JUL-2023
DATE OF MANUFACTURE			01-AUG-2018
APPEARANCE			WHITE TO SLIGHTLY YELLOW POWDER
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
CLASS 3 (solvent) / ACETIC ACID			<5000 ppm

Certificate of Analysis Results Entered By:

MPEREZ  
Melchor Perez  
28-APR-20 13:49:41

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MPEREZ  
Melchor Perez  
28-APR-20 13:49:55

**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 Unichem Laboratories Limited at Plot No. 99, MIDC Area, Roha, Raigad, Maharashtra 402116, India. 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

Preparation Date: 9/21/2016

Revision date 09/06/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** M1511  
**Product Name:** METRONIDAZOLE, USP

#### Other means of identification

**Synonyms:** 1-(2-Hydroxy-1-ethyl)-2-methyl-5-nitroimidazole  
 1-(2-Hydroxyethyl)-2-methyl-5-nitroimidazole  
 1-(beta-Ethylol)-2-methyl-5-nitro-3-azapyrrole  
 1-(beta-Hydroxyethyl)-2-methyl-5-nitroimidazole  
 1-(beta-Oxyethyl)-2-methyl-5-nitroimidazole  
 1-(hydroxyethyl)-2-methyl-5-nitro-imidazole  
 1-Hydroxyethyl-2-methyl-5-nitroimidazole  
 2-Methyl-1-(2-hydroxyethyl)-5-nitroimidazole  
 2-Methyl-3-(2-hydroxyethyl)-4-nitroimidazole  
 2-Methyl-5-nitroimidazole-1-ethanol  
 Imidazole-1-ethanol, 2-methyl-5-nitro-  
**CAS #:** 443-48-1  
**RTECS #** N15600000  
**CI#:** Not available

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

**Recommended use:** Research and Development.  
**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:** Tom Tyner (USA - West Coast)

**Contact Person:** Ibad Tirmiz (USA - East Coast)

### 2. HAZARDS IDENTIFICATION

#### Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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

Carcinogenicity	Category 2
-----------------	------------

#### Label elements

**Warning****Hazard statements**

Suspected of causing cancer

**Hazards not otherwise classified (HNOC)**

May be harmful if swallowed

**Other hazards**

Not available

**Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

**Precautionary Statements - Response***IF exposed or concerned: Get medical attention***Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS No	Weight-%
Metronidazole	443-48-1	100

**4. FIRST AID MEASURES****First aid measures****General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**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 not breathing, give artificial respiration. If breathing is difficult, give oxygen. 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**

<b>Symptoms</b>	May cause eye/skin irritation
	May cause respiratory irritation
	May cause stomach pain
	Nausea
	Vomiting
	Dizziness
	Headache
	Somnolence
	Tremors
	Convulsions
	Irritability
	Hallucinations

**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 (CO<sub>2</sub>). Nitrogen oxides (NO<sub>x</sub>).

**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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid dust formation. Avoid breathing dust. 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. 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. Ensure adequate ventilation. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice:**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe dust. Do not ingest. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Sensitive to light. Store in light-resistant containers. Protect from light. Keep away from heat and sources of ignition. Keep container tightly closed in a dry and well-ventilated place. Store away from incompatible materials. Store at room temperature in the original container.

#### **Incompatible Materials:**

Strong oxidizing agents  
Bases  
Aluminum

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Metronidazole	443-48-1	None	None	None	None

##### **Canada**

Component	CAS No	Canada - Alberta	Canada - British	Canada - Ontario	Canada - Quebec
-----------	--------	------------------	------------------	------------------	-----------------

			<b>Columbia</b>		
Metronidazole	443-48-1	None	None	None	None

### Australia and Mexico

Component	CAS No	<b>Australia</b>	<b>Mexico</b>
Metronidazole	443-48-1	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

<b>Eye protection:</b>	Goggles or Safety glasses with side-shields.
<b>Skin and body protection:</b>	Chemical resistant apron Long sleeved clothing Gloves
<b>Respiratory protection:</b>	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Powder.	<b>Color:</b> White. Pale Yellow.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available.	<b>Formula</b> C6H9N3O3
<b>Molecular/Formula weight (g/mole):</b> 171.15	<b>Flammability (solid, gas)</b> no data 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>Melting point/range(°C/°F):</b> 159° - 162°F (318° - 323.6°F)	<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/cm3):</b> No information available

#### Specific gravity:

**Product code:** M1511

**Product name:** METRONIDAZOLE,  
USP

**Page** 5 / 12

No information available

**pH**  
No information available

**Vapor pressure @ 20°C (kPa):**  
No information available

**Evaporation rate:**  
No information available

**Vapor density:**  
No information available

**VOC content (g/L):**  
No information available

**Odor threshold (ppm):**  
No information available

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

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Sparingly soluble in alcohol  
Sparingly soluble in Dimethylformamide  
Slightly soluble in chloroform  
Slightly soluble in Ether  
Slightly soluble in Acetone  
Soluble in dilute acids

## 10. STABILITY AND REACTIVITY

**Reactivity**  
Reactive with oxidizing agents

### Chemical stability

**Stability:** Sensitive to light. Stable under recommended storage conditions.

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

**Conditions to avoid:** Heat. Exposure to light. Incompatible materials. Ignition sources.

**Incompatible Materials:** Strong oxidizing agents  
Bases  
Aluminum

**Hazardous decomposition products:** Carbon oxides. Nitrogen oxides (NOx).

### 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. Skin.

### Acute Toxicity

The following values are calculated based on chapter 3.1 of the GHS document  
**Component Information**

Metronidazole	
CAS No	443-48-1

**Product code:** M1511

**Product name:** METRONIDAZOLE,  
USP

**Page** 6 / 12

LD50/oral/rat = 3 g/kg Oral LD50 Rat  
LD50/oral/mouse = 3800 mg/kg Oral LD50 Mouse  
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 Toxicity = 3000 mg/kg

LD50/oral/mouse =  
Value - Acute Tox = 3800 mg/kg

LD50/dermal/rabbit  
Value - Acute Toxicity = No information available

LD50/dermal/rat  
VALUE - Acute Tox = 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

<b>Skin Contact:</b>	May cause skin irritation.
<b>Eye Contact:</b>	May cause eye irritation.
<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Ingestion</b>	May cause digestive (gastrointestinal) tract irritation. May cause mild stomach pain. Ingestion may cause nausea, vomiting. May cause metallic taste. May affect liver. May affect behavior/central nervous system (dizziness, headache).
<b>Aspiration hazard</b>	No information available.

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

<b>Chronic Toxicity</b>	Prolonged or repeated ingestion may cause weight loss. Prolonged or repeated ingestion may affect the urinary system. Prolonged or repeated ingestion may affect behavior/central nervous system.
<b>Sensitization:</b>	No information available.
<b>Mutagenic Effects:</b>	No information available

**Carcinogenic effects:** Suspected of causing cancer.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Metronidazole	443-48-1	Supplement 7 [1987] Monograph 13 [1977]	Not listed	Reasonably Anticipated To Be A Human Carcinogen	Present	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available

**Developmental Effects:** No information available

**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

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

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

**Target Organs:** No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility in soil** No information available

**Other adverse effects** 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Metronidazole	443-48-1	None	None	None	None

## 14. TRANSPORT INFORMATION

### DOT

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class	No information available
Subsidiary Class	No information available
Packing group:	No information available
Emergency Response Guide Number	No information available
Marine Pollutant	No data available
DOT RQ (lbs):	No information available
Special Provisions	No Information available
Symbol(s):	No information available
Description:	No information available

### TDG (Canada)

UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
Marine Pollutant	No Information available
Description:	No information available

### ADR

UN Number	Not regulated
Proper Shipping Name:	No information available
Transport hazard class(es)	No information available
Packing group	No information available
Subsidiary Risk:	No information available

### 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 Number	Not Regulated
Proper Shipping Name:	No information available
Transport hazard class(es)	No information available
Subsidiary Risk:	No information available
Packing group	No information available

### ICAO (air)

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 Number	Not Regulated
-----------	---------------

**Proper Shipping Name:** No information available  
**Transport hazard class(es)** No information available  
**Subsidiary Risk:** No information available  
**Packing group** No information available  
**Precautionary Statements - Response** No information available  
**Special Provisions** No information available

15. REGULATORY INFORMATION


International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
Metronidazole	443-48-1	Not Listed	Present KE-20530	Present	Not present	Present	Present	Present 207-136-1

U.S. Regulations

*Metronidazole*  
**Massachusetts RTK:** Present  
**Pennsylvania RTK:** Special hazardous substance  
**Pennsylvania RTK - Special Hazardous Substances** Present  
**Minnesota - Hazardous Substance List:** Present  
**New York Release Reporting - List of Hazardous Substances:**  
 1 lb RQ  
**California Directors List of Hazardous Substances:** Present

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

**Chemicals Known to the State of California to Cause Cancer:**  
 **WARNING:** This product contains a chemical known to the State of California to cause cancer. (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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Metronidazole	443-48-1	carcinogen	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Metronidazole	443-48-1	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Metronidazole	443-48-1	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification  
Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has not been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Metronidazole	443-48-1	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Metronidazole	443-48-1	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Metronidazole	443-48-1	Not listed

#### EU Classification

##### EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Metronidazole	443-48-1	

##### EU - CLP (1272/2008)

#### R-phrases(s)

R40 - Limited evidence of a carcinogenic effect

#### S -phrase(s)

S 2 - Keep out of the reach of children.

S36/37 - Wear suitable protective clothing and gloves

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Metronidazole	443-48-1		No information	

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

#### Indication of danger:

Xn - Harmful

Xn



#### 16. OTHER INFORMATION

Preparation Date: 9/21/2016  
Revision date 09/06/2019  
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**

## 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
M1511	Metronidazole, 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.