



# Scientific Documentation

M1435, Methotrexate, 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

Ver4.04 2.April.2018



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, CQA  
Director, Global Supplier Quality Assurance  
[awang@spectrumchemical.com](mailto:awang@spectrumchemical.com)

**M1435, Methotrexate, USP**

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



## Specification for Methotrexate, USP (M1435)

Item Number	M1435
Item	Methotrexate, USP
CAS Number	59-05-2
Molecular Formula	$C_{20}H_{22}N_8O_5$
Molecular Weight	454.44
MDL Number	
Synonyms	(+)-Amethopterin ; 4-Amino-10-methylfolic Acid

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
RELATED COMPOUNDS		TO PASS TEST
ENANTIOMERIC PURITY		TO PASS TEST
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
WATER DETERMINATION		12.0 %
IDENTIFICATION		TO PASS TEST
EXPIRATION 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: 3/6/2013

Revision Date: 4/4/2016

Revision Number: G3

### 1. IDENTIFICATION

**Product identifier**

**Product code:** M1435  
**Product Name:** METHOTREXATE, USP

**Other means of identification**

**Synonyms:**

Amethopterin; (+)-Amethopterin; Amethopterine; 4-Amino-4-deoxy-N-methylpteroylglutamate; 4-Amino-4-deoxy-N-methylpteroylglutamic acid; 4-Amino-10-methylfolic acid; 4-Amino-N-methylpteroylglutamic acid; Antifolan; L-(+)-N-(p-(((2,4-Diamino-6-pteridiny)methyl)methylamino)benzoyl)glutamic acid; N-(p-(((2,4-Diamino-6-pteridiny)methyl)methylamino)benzoyl)-L-(+)-glutamic acid; N-(p-(((2,4-Diamino-6-pteridyl)methyl)methylamino)benzoyl)glutamic acid; N-Bismethylpteroylglutamic acid; Ledertrexate; Methylaminopterin; Methylaminopterinum; L-Glutamic acid, N-(4-(((2,4-diamino-6-pteridiny)methyl)methylamino)benzoyl)-; Glutamic acid, N-(p-(((2,4-diamino-6-pteridiny)methyl)methylamino)benzoyl)-, L-(+)-

**CAS #:** 59-05-2  
**RTECS #** MA1225000  
**CI#:** Not available

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

**Recommended use:** Medication.  
**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
Reproductive toxicity	Category 1B

## Label elements

### Danger

#### Hazard statements

Toxic if swallowed

May damage fertility or the unborn child



#### 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

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

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

#### Precautionary Statements - Response

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

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

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

Rinse mouth

#### Precautionary Statements - Storage

Store locked up

#### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Methotrexate 59-05-2	59-05-2	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. **WARNING!** It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Toxic if swallowed. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

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

**Symptoms** Causes digestive (gastrointestinal) tract irritation. May cause nausea and vomiting. May cause loss of appetite. Pale skin. redness. Skin rash. May cause central nervous system effects. Convulsions. Dizziness. Drowsiness. Headache. Weakness. Fatigue. Blurred vision. Easy bruising or bleeding. May cause cardiovascular effects. Hypotension.

**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. Alcohol-resistant foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon monoxide; Carbon dioxide; Nitrogen oxides

**Specific hazards:** May be combustible at high temperatures

**Special Protective Actions for Firefighters**

**Specific Methods:** For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out. Dike fire-control water for later disposal; do not scatter the material.

**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:** Keep people away from and upwind of spill/leak. 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. Prevent product from entering 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. Avoid creating dust. 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. Keep away from incompatible materials.

#### **Safe Handling Advice**

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

### Conditions for safe storage, including any incompatibilities

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

Keep container tightly closed in a dry and well-ventilated place. Store away from incompatible materials. Protect from light. Sensitive to light. Store in light-resistant containers.

#### **Incompatible Materials:**

Oxidizing agents. Acids.

## 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
Methotrexate 59-05-2	None	None	None	None

#### **Canada**

**Canada Occupational Exposure Limits:** Not determined

Components	Alberta	British Columbia	Ontario	Quebec
Methotrexate 59-05-2	None	None	None	None

#### **Australia and Mexico**



Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Methotrexate 59-05-2	None	None

**Appropriate engineering controls**

**Engineering measures to reduce exposure:**

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:** Safety glasses Safety glasses with side-shields
- Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- Respiratory protection:** 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> Crystalline powder.	<b>Color:</b> Yellow.
<b>Odor:</b> None.	<b>Taste</b> No information available	<b>Formula:</b> C20-H22-N8-O5
<b>Molecular/Formula weight:</b> 454.44	<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> 185-204 °C/365-399 °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	<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> Insoluble in water Insoluble in Alcohol Insoluble in Ether Insoluble in Chloroform	

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with acids  
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. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to light.

#### **Incompatible Materials:**

Oxidizing agents. Acids.

#### **Hazardous decomposition products:**

Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). When heated to decomposition it emits toxic fumes.

### 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

*Methotrexate - 59-05-2*

**LD50/oral/rat** = 135 mg/kg Oral LD50 Rat

**LD50/oral/mouse** = 146 mg/kg

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

**LD50/dermal/rat** = =135mg/kgOral LD50Rat

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

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

**Other LD50 or LC50information** = No information available

#### Product Information

**LD50/oral/rat** =

**VALUE- Acute Tox Oral** = 135mg/kg

**LD50/oral/mouse** =

**Value - Acute Tox Oral** = 146mg/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. Causes digestive (gastrointestinal) tract irritation. Ingestion may cause nausea, vomiting, diarrhea. May cause abdominal pain. May cause stomatitis. May cause oral ulceration. May cause gastrointestinal bleeding. May cause blurred vision. May cause skin rash, redness or itching. It may affect the bone marrow (bone marrow depression). It may affect the blood (changes in white and red blood cell count). It may affect the blood (thrombocytopenia, leukocytopenia, anemia, pancytopenia). May cause easy bruising or bleeding. May affect the liver (fatty liver degeneration, hepatitis, liver function tests impaired). May affect urinary system (kidneys). It may affect the brain. May affect respiration (difficult or labored breathing resulting in shortness of breath). May affect respiration (fibrosis, pneumoconiosis, respiratory obstruction). May affect behavior/central nervous system (fatigue, weakness). May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (somnolence, convulsions). May affect behavior/central nervous system (moodiness, cognitive dysfunction). It may affect the immune system and cause decreased immune response. May cause decreased resistance to infection. May affect the cardiovascular system (hypotension).

**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 cause nausea, vomiting, diarrhea  
 Prolonged or repeated ingestion may affect the liver, and kidneys  
 Prolonged or repeated ingestion may affect the bone marrow  
 Prolonged or repeated ingestion may affect the blood (changes in red blood cell count)  
 Prolonged or repeated ingestion may affect the blood (changes in white blood cell count)  
 Prolonged or repeated ingestion may affect the blood (anemia)  
 Prolonged or repeated ingestion may affect the blood (changes in clotting factors)  
 Prolonged or repeated ingestion may affect the blood (leukopenia, thrombocytopenia)  
 Prolonged or repeated ingestion may affect the brain  
 Prolonged or repeated ingestion may affect behavior/central nervous system (headache, somnolence, convulsions/seizures)  
 Prolonged or repeated ingestion may cause loss of appetite

**Sensitization:**

No information available

**Mutagenic Effects:**

May affect genetic material  
 Mutations in microorganisms  
 Experiments with bacteria and/or yeast have shown mutagenic effects  
 Mutagenic effects in mammalian somatic cells  
 Experiments with animal lymphocytes have shown mutagenic effects

**Carcinogenic effects:**

Not classifiable as to its carcinogenicity to humans. Equivocal tumorigenic agent by Registry of Toxic Effects of Chemical Substances (RTECS) criteria.

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Methotrexate	Supplement 7 [1987] Monograph 26 [1981]	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*  
*IARC (International Agency for Research on Cancer)*  
*Group 3 - Not classifiable as to its carcinogenicity to humans*  
*NTP (National Toxicology Program)*

**Reproductive toxicity** May damage fertility or the unborn child

**Reproductive Effects:** No information available  
**Developmental Effects:** May cause harm to the unborn child  
**Teratogenic Effects:** Can cause birth defects

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available  
**STOT - repeated exposure** No information available  
**Target Organs:** Bone Marrow. Blood. Liver. Kidneys.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:**

**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
Methotrexate	None	None	None	None

**14. TRANSPORT INFORMATION**

**DOT**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solids, organic, n.o.s. (amrinone)  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**ERG No:** 154  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** G

## 14. TRANSPORT INFORMATION

### TDG (Canada)

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**Marine Pollutant:** No Information available

### ADR

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Packing Group:** III  
**Subsidiary Risk:** No information available

### IMO / IMDG

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**Marine Pollutant:** No information available  
**EMS:** F-A

### RID

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** 6.1  
**Packing Group:** III

### ICAO

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III

### IATA

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**ERG Code:** 6L  
**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.
<i>Methotrexate</i>	Present	Present KE-09753	Not present	Not present	Not present	Present	Present 200-413-8

## U.S. Regulations

Methotrexate

Massachusetts RTK: Present

### 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:

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Methotrexate	Not Listed	developmental toxicity	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>
Methotrexate	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
Methotrexate	Not Applicable	Not Applicable

## Canada

#### WHMIS hazard class:

D1B Toxic materials

D2A Very toxic materials

#### 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)
Methotrexate	Not Listed	Present

Components	CEPA Schedule I - Toxic Substances
Methotrexate	Not listed

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

## EU Classification

**R-phrase(s)**

R25 - Toxic if swallowed.

R63 - Possible risk of harm to the unborn child.

R68 - Possible risk of irreversible effects.

**S -phrase(s)**

S36 - Wear suitable protective clothing.

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

S53 - Avoid exposure - obtain special instructions before use.

Components	Classification	Concentration Limits:	Safety Phrases
Methotrexate	R25 R63 R68	No information	36 45 53

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

**Indication of danger:**

T - Toxic

Xn - Harmful.

**16. OTHER INFORMATION**



## 16. OTHER INFORMATION

**Preparation Date:** 3/6/2013  
**Revision Date:** 4/4/2016  
**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: M1435, Methotrexate, 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, CQA  
Director, Global Supplier Quality Assurance  
[awang@spectrumchemical.com](mailto:awang@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.



# 管理体系认证 注册证书

兹证明，以下组织：

## 斯百全化学（上海） 有限公司

上海市松江区申港路3802弄A20

的管理体系，符合以下标准要求并予以注册：

### ISO 9001:2015

此管理体系适用于：

药用辅料销售，化学品销售

统一社会信用代码：

91310000777627048K

证书编号：

111310001

首次认证日期：

2015年11月17日

认证决定日期：

2017年12月26日

签发日期：

2017年12月26日

有效期至：

2018年11月10日



014

**Calin Moldovean**

President, Business Assurance

Intertek Certification Limited, 10A Victory  
Park, Victory Road, Derby DE24 8ZF, United  
Kingdom

Intertek Certification Limited  
是 UKAS 认可的认证机构，  
注册号为 014



# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Spectrum China Ltd.

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

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

## ISO 9001:2015

The management system is applicable to:

Sales for Pharmaceutical Excipients, Sales for Chemicals

**Unified Social Credit Identifier:**

91310000777627048K

**Certificate Number:**

111310001

**Initial Certification Date:**

17 November 2015

**Date of Certification Decision:**

26 December 2017

**Issuing Date:**

26 December 2017

**Valid Until:**

10 November 2018



014

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

**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.



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

April 2, 2018

**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
M1435	Methotrexate, 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





July 25, 2016

Re: Methotrexate, USP- M1435

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

Methotrexate, USP- M1435

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 Mfr. Corp.

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

Item Number	M1435	Lot Number	2FE0058
Item	Methotrexate, USP		
CAS Number	59-05-2		
Molecular Formula	C <sub>20</sub> H <sub>22</sub> N <sub>8</sub> O <sub>5</sub>	Molecular Weight	454.44

Test	Specification		Result
	min	max	
ASSAY (ANHYDROUS BASIS)	98.0 - 102.0 %		99.7 %
ENANTIOMERIC PURITY		TO PASS TEST	PASSES TEST
RELATED COMPOUNDS		TO PASS TEST	PASSES TEST
RESIDUE ON IGNITION		0.1 %	0.07 %
HEAVY METALS		20 ppm	<20 ppm
WATER		12.0 %	9.54 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			27-AUG-2018
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm
CLASS 3 (solvent) / ETHYL ETHER			<5000 ppm
APPEARANCE			FINE YELLOW POWDER
DATE OF MANUFACTURE			28-AUG-2015

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 SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

## 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.

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

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: M1435, Methotrexate, USP

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

The product, M1435, Methotrexate, USP, is assigned a 36 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