SAFETY DATA SHEET

Preparation Date: 3/6/2013
Revision date: 9/25/2019
Revision Number: G4

1. IDENTIFICATION

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-pteridinyl)methyl)methylamino)benzoyl)glutamic acid;
N-(p-(((2,4-Diamino-6-pteridinyl)methyl)methylamino)benzoyl)-L-(+)-glutamic acid;
N-(p-(((2,4-Diamino-6-pteridinyl)methyl)methylamino)benzoyl)glutamic acid;
N-Bismethylpteroylglutamic acid; Ledertrexate; Methylaminopterin;
Methylaminopterinum; L-Glutamic acid, N-(4-(((2,4-diamino-6
pteridinyl)methyl)methylamino)benzoyl)-; Glutamic acid,
N-(p-(((2,4-diamino-6-pteridinyl)methyl)methylamino)benzoyl)-, L-(+)-

CAS #: 59-05-2
RTECS #: MA1225000
Cl#: 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: 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)

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 attention
- Specific treatment (see .? on this label)
- IF SWALLOWED: Immediately call a POISON CENTER or physician
- Rinse mouth

**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

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Weight-%</th>
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<tbody>
<tr>
<td>Methotrexate</td>
<td>59-05-2</td>
<td>100</td>
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### 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 (CO2). 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 (NOx).

**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: 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 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


Incompatible Materials: Oxidizing agents Acids

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WEEL</th>
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</tbody>
</table>

Canada

Product code: M1435  Product name: METHOTREXATE, USP
### 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 with side-shields. or Goggles

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

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

**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

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<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
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<tr>
<td>Solid</td>
<td>Crystalline powder.</td>
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<thead>
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<th>Product name:</th>
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<tbody>
<tr>
<td>M1435</td>
<td>METHOTREXATE, USP</td>
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</table>
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. Exposure to light.
- Incompatible Materials: Oxidizing agents, Acids

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

<table>
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<tr>
<th>Component</th>
<th>CAS No</th>
<th>LD50/oral/rat (mg/kg)</th>
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<th>LD50/dermal/rabbit (mg/kg)</th>
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<td>146</td>
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Product code: M1435  Product name: METHOTREXATE, USP
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 = 135 mg/kg

LD50/oral/mouse =
   Value - Acute Tox = 146 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

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 or foggy 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.

Product code: M1435 Product name: METHOTREXATE, USP
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 (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.

<table>
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<th>Component</th>
<th>CAS No</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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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)
OSHA (Occupational Safety and Health Administration of the US Department of Labor)

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:

12. ECOLOGICAL INFORMATION

Product code: M1435
Product name: METHOTREXATE, USP
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

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<td>59-05-2</td>
<td>None</td>
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</table>

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (methotrexate)
Hazard Class 6.1
Subsidiary Class No information available
Packing group: III
Emergency Response Guide Number 154
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions IB8, IP3, T1, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, III

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
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ADR

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.

Product code: M1435  Product name: METHOTREXATE, USP
Transport hazard class(es): 6.1
Packing group: III
Subsidiary Risk: No information available
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

IMDG
UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (methotrexate)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant: No information available
EMS: F-A
Special Provisions: 223, 274
Description: UN2811, Toxic solid, organic, n.o.s. (METHOTREXATE), 6.1, III

RID
UN Number: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es): 6.1
Subsidiary Risk: 6.1
Packing group: III
Special Provisions: 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ICAO (air)
UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III
Special Provisions: A3, A5

IATA
UN Number: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es): 6.1
Subsidiary Risk: No information available
Packing group: III
Precautionary Statements - Response: 6L
Special Provisions: No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

15. REGULATORY INFORMATION

International Inventories

<table>
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<tr>
<th>Component</th>
<th>CAS No</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>China IECSC</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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<td>Present KE-09753</td>
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<td>Not present</td>
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<td>Present 200-413-8</td>
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</table>

U.S. Regulations

Product code: M1435  
Product name: METHOTREXATE, USP
**Methotrexate**

**Massachusetts RTK:** Present


**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)

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<tr>
<th>Component</th>
<th>CAS No</th>
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<th>Male Reproductive Toxicity</th>
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**CERCLA/SARA**

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<th>Component</th>
<th>CAS No</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
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**U.S. TSCA**

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<th>Component</th>
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<th>TSCA 8(d) - Health and Safety Reporting</th>
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**Canada**

**WHIMIS 2015 - GHS Classifications**

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**

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<th>CAS No</th>
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<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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**EU Classification**

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

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<th>CAS No</th>
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**Product code:** M1435  
**Product name:** METHOTREXATE, USP  
**Page:** 11 / 12
Methotrexate 59-05-2

EU - CLP (1272/2008)

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

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

Indication of danger:
T - Toxic
Xn - Harmful

16. OTHER INFORMATION

Preparation Date: 3/6/2013
Revision date 9/25/2019
Prepared by: Sonia Owen

Disclaimer:
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End of Safety Data Sheet

Product code: M1435  Product name: METHOTREXATE, USP