

# Scientific Documentation

## 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



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## Specification for Methotrexate, USP (M1435)

Item Number	M1435
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
MDL Number	
Synonyms	4-Amino-10-methylfolic Acid ; (+)-Amethopterin

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
RELATED COMPOUNDS:		
METHOTREXATE RELATED COMPOUND B		0.3 %
METHOTREXATE RELATED COMPOUND C		0.5 %
METHOTREXATE RELATED COMPOUNDS E FREE BASE		0.3 %
METHOTREXATE RELATED DIMETHYLAMIDE AND RELATED COMPOUND I		0.2 %
METHOTREXATE RELATED COMPOUND H		0.2 %
ANY UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		1.0 %
ENANTIOMERIC PURITY (R-METHOTREXATE CONTENT)		3.0 %
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

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<b><i>Corporate Headquarters:</i></b>	<b><i>West Coast Facility:</i></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	M1435	Lot Number	4MG0043
Item	Methotrexate, USP	Manufacturer Lot	EP230313
CAS Number	59-05-2	Manufacturer Code	15151
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 %	98.5 %
RELATED COMPOUNDS:			.
METHOTREXATE RELATED COMPOUND B		0.3 %	0.0 %
METHOTREXATE RELATED COMPOUND C		0.5 %	0.0 %
METHOTREXATE RELATED COMPOUNDS E FREE BASE		0.3 %	0.0 %
METHOTREXATE RELATED DIMETHYLAMIDE AND RELATED COMPOUND I		0.2 %	0.0 %
METHOTREXATE RELATED COMPOUND H		0.2 %	0.0 %
ANY UNSPECIFIED IMPURITY		0.10 %	0.0 %
TOTAL IMPURITIES		1.0 %	0.0 %
ENANTIOMERIC PURITY (R-METHOTREXATE CONTENT)		3.0 %	0.0 %
RESIDUE ON IGNITION		0.1 %	0.03 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
WATER DETERMINATION		12.0 %	8.85 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			13-MAR-2026
DATE OF MANUFACTURE			14-MAR-2023
APPEARANCE			FINE YELLOW POWDER
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
MONOGRAPH EDITION			USP 2023
CLASS 3 (solvent) / ACETONE			<5000 ppm
CLASS 3 (solvent) / ETHANOL			<5000 ppm

TEST	SPECIFICATION		RESULT
	MIN	MAX	
CLASS 3 (solvent) / ETHYL ETHER			<5000 ppm

Certificate of Analysis Results Entered By:

KMORALES  
Keyla Morales  
19-SEP-23 09:52:55

Certificate of Analysis Results Approved By:

KMORALES  
Keyla Morales  
20-SEP-23 10:05:20

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



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

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

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 Huzhou Zhanwang Pharmaceutical Co., Ltd. at West Development Area Rd, Linghu Town, Huzhou, Zhejiang 313018, China (CHN). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

# spectrum®



Revision date 05-January-2023

Revision Number 4

## 1. Identification

### Product identifier

Product Name METHOTREXATE, USP

### Other means of identification

Product Code(s) M1435

UN/ID no UN2811

Synonyms None

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

Recommended use No information available

Restrictions on use No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Acute toxicity - Oral	Category 3
Reproductive toxicity	Category 1A

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

Danger

#### Hazard statements

Toxic if swallowed  
May damage fertility or the unborn child



**Appearance** powder

**Physical state** Solid

**Odor** No information 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  
Rinse mouth

**Precautionary Statements - Storage**

Store locked up.

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%
Methotrexate	59-05-2	100

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get medical attention.

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

**Symptoms** No information available.

**Indication of any immediate medical attention and special treatment needed**



**Note to physicians**

Treat symptomatically.

## 5. Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Ensure adequate ventilation.
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### Methods and material for containment and cleaning up

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

## 7. Handling and storage

### Precautions for safe handling

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.
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### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.
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## 8. Exposure controls/personal protection

### Control parameters

<b>Exposure Limits</b>	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure
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limits from the sources listed here.

### **Appropriate engineering controls**

<b>Engineering controls</b>	Showers
	Eyewash stations
	Ventilation systems.

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

<b>Eye/face protection</b>	No special protective equipment required.
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<b>Hand protection</b>	Wear suitable gloves.
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<b>Skin and body protection</b>	Wear suitable protective clothing.
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<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
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**General hygiene considerations** Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state		Solid
Appearance		powder
Color		Yellow
Odor		No information available
Odor threshold		No information available

Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	>185 °C / °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Practically insoluble in water	None known
Solubility(ies)	Slightly soluble in Dimethyl sulfoxide (DMSO)	None known
	soluble in dimethylformamide	
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

### Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available

Liquid Density No information available  
Bulk density No information available

## 10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

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

Symptoms No information available.

### Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methotrexate 59-05-2	= 135 mg/kg ( Rat )	-	-

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Methotrexate 59-05-2	-	Group 3 - Not classifiable - Supplement 7 [1987] Monograph 26 [1981]	-	-

#### Legend

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.

<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

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

## 13. Disposal considerations

### Waste treatment methods

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

## 14. Transport information

### DOT

<b>UN/ID no</b>	UN2811
<b>Proper shipping name</b>	Toxic solids, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	III
<b>Special Provisions</b>	IB8, IP3, T1, TP33
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description</b>	UN2811, Toxic solids, organic, n.o.s., 6.1, III
<b>Emergency Response Guide Number</b>	151

### TDG

<b>UN/ID no.</b>	UN2811
<b>Proper shipping name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group</b>	III
<b>Special Provisions</b>	16
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### MEX

<b>UN-No</b>	UN2811
<b>Proper Shipping Name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	223, 274
<b>Packing Group</b>	III
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III

### ICAO (air)

<b>UN/ID no.</b>	UN2811
<b>Hazard class</b>	6.1

<b>Packing Group</b>	III
<b>Special Provisions</b>	A3, A5

**IATA**

<b>UN number</b>	UN2811
<b>Hazard Class</b>	6.1
<b>Packing group</b>	III
<b>Emergency Response Guide Number</b>	6L
<b>Special Provisions</b>	A3, A5

**IMDG**

<b>UN number</b>	UN2811
<b>Hazard Class</b>	6.1
<b>Packing group</b>	III
<b>EmS-No</b>	F-A, S-A
<b>Special Provisions</b>	223, 274
<b>Marine Pollutant</b>	NP1

**RID**

<b>UN number</b>	UN2811
<b>Proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>Hazard Class</b>	6.1
<b>Packing group</b>	III
<b>Classification code</b>	T2
<b>Special Provisions</b>	274, 614
<b>Description</b>	UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III
<b>Labels</b>	6.1

**ADR**

<b>UN number</b>	UN2811
<b>Proper shipping name</b>	Toxic solid, organic, n.o.s.
<b>Hazard Class</b>	6.1
<b>Packing group</b>	III
<b>Classification code</b>	T2
<b>Tunnel restriction code</b>	(E)
<b>Special Provisions</b>	274, 614
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III, (E)
<b>Labels</b>	6.1

**ADN**

<b>UN/ID No</b>	UN2811
<b>Proper shipping name</b>	Toxic solid, organic, n.o.s.
<b>Hazard Class</b>	6.1
<b>Packing Group</b>	III
<b>Classification code</b>	T2
<b>Special Provisions</b>	274, 614, 802
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, III
<b>Hazard label(s)</b>	6.1
<b>Limited quantity (LQ)</b>	5 kg
<b>Equipment Requirements</b>	PP, EP

**15. Regulatory information****International Inventories**

<b>TSCA</b>	Complies
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<b>DSL/NDL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product does not comply with china:
<b>KECL</b>	Complies
<b>PICCS</b>	Does not Comply

**AICS**

All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals:

Chemical name	California Proposition 65
Methotrexate - 59-05-2	developmental toxicity

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Methotrexate 59-05-2	-	Present	-

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information****NFPA**

**Health hazards** 0

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

**HMIS****Health hazards** \***Flammability** 0**Physical hazards** 0**Personal protection** X*Chronic Hazard Star Legend*

\* = Chronic Health Hazard

**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

**Revision date** 05-January-2023**Revision Note** No information available.**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**



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

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
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

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,

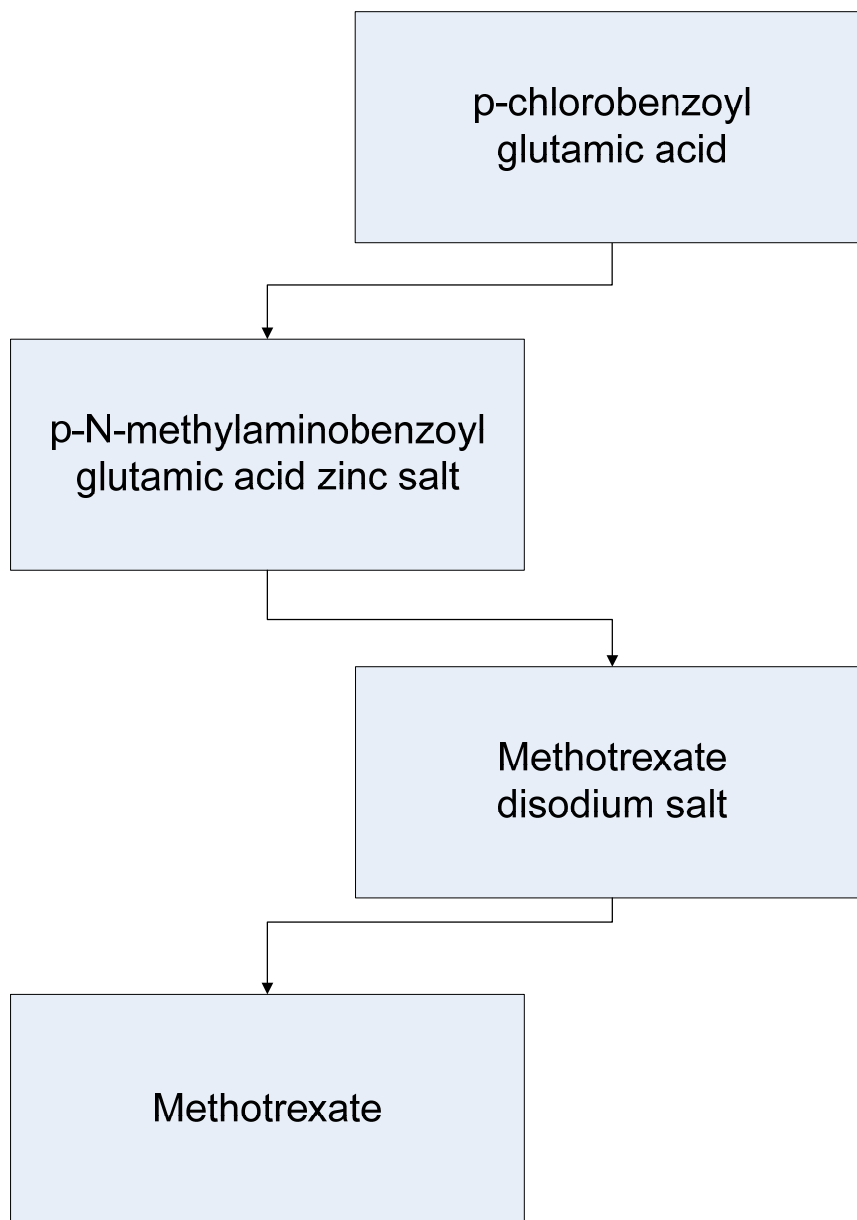
A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez  
Quality Assurance Specialist



## Manufacturing Process Flowchart

### Methotrexate, USP - M1435



#### ***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

## M1435, Methotrexate, USP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Methotrexate, USP (Cat# M1435)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Chromium	Cr	3	< 0.15 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

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

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

**CORPORATE HEADQUARTERS**

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

**WEST COAST FACILITY**

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**RE: Residual Solvents - Methotrexate, USP (Cat# M1435)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
Ethyl Ether	3	< 5000 ppm

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

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

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

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

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## 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.

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

**A**

**C** **DANGER**  
**•Toxic if swallowed • May damage 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 • Wash face, hands and any exposed skin thoroughly after handling.  
**FIRST AID:** IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth. If exposed or concerned: Get medical attention.

**KEEP FROM CHILDREN**  
**WARNING:**  
 Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

**L**

**spectrum®**  
 CHEMICAL MFG CORP

**M1435** **D** **F** **500 G**

**E** **Methotrexate**  
 [(+)-Amethopterin; 4-Amino-10-methylfolic Acid]  
 USP  
 CAS 59-05-2

**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.**

**J** DOT: UN2811, Toxic solid, organic, n.o.s. (methotrexate), 6.1, PG III

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

**USP 800**  
 HAZARDOUS DRUG

**K** **C<sub>20</sub>H<sub>22</sub>N<sub>8</sub>O<sub>5</sub>** **F.W. 454.44**

Manufacturer/Supplier Code ..... ?  
 Manufacturer Lot Number ..... ?  
 Assay (Anhydrous Basis) ..... 98.0-102.0%

**MAXIMUM LIMITS**

Related Compounds:  
 Methotrexate Related Compound B ..... 0.3%  
 Methotrexate Related Compound C ..... 0.5%  
 Methotrexate Related Compound E Free Base ..... 0.3%  
 Methotrexate Dimethylamide and Related Compound I ..... 0.2%  
 Methotrexate Related Compound H ..... 0.2%  
 Any Unspecified Impurity ..... 0.10%  
 Total Impurities ..... 1.0%  
 Enantiomeric Purity (R-Methotrexate Content) ..... 3.0%  
 Residue on Ignition ..... 0.1%  
 Elemental Impurities ..... As reported  
 Water Determination ..... 12.0%  
 Residual Solvents ..... To pass test

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

**I** **Repackaged by Spectrum as:** **M**  
**B 12/I7GHS-A A O** **Lot No. 062233**

**SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901**

- |   |  |   |
|---|--|---|
| <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

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