

Methotrexate Sodium for Injection

Preparation Date 15-Jan-2007

Revision Date 31-Mar-2008

Revision Number 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name Methotrexate Sodium for Injection
Common Name Not available
Chemical Name Not applicable
Synonyms Methotrexate
Product Use Pharmaceutical product
Classification Antineoplastic Agent - Cytostatic

Supplier Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Methotrexate	59-05-2	2004138	7.5 - 25.5 mg/ml	T, Xi; R23/24/25, 40, 46, 61; S45, 53

3. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Biopharmaceutical liquid

Physical State Liquid

Odor Not available

Potential Physical Hazards

None known

Potential Health Effects

Eyes

Irritating to eyes.

Skin

Irritating to skin.

Inhalation

Irritating to respiratory system.

Ingestion

The most common effects may include bone marrow depression, hepatotoxicity, pulmonary toxicity, cutaneous and sensitivity reactions, mouth ulceration, nausea, vomiting, diarrhea, central nervous system effects, back pain, blurred vision, confusion, dizziness, drowsiness, fever, headache, and unusual tiredness or weakness.

May cause harm to the unborn child. May cause harm to breastfed babies. May cause inheritable genetic damage.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s)

Systemic.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects

There is no known ecological information for this product.

4. FIRST AID MEASURES**Eye Contact**

In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact

Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation

Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion

If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES**Flammable Properties**

Not flammable

Extinguishing Media**Suitable Extinguishing Media
Unsuitable Extinguishing
Media**

Use water spray, foam, dry chemical or carbon dioxide.
Do NOT use water jet.

Fire Fighting

Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products

Carbon oxides, nitrogen oxides.

**Protective Equipment and
Precautions for Firefighters**

In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES**Personal Precautions**

Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions

Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment

Not available

Methods for Cleaning up

Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE**Handling**

For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage

No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Methotrexate	Exposure Guideline 0.1 mcg/m ³
Engineering Controls	Enclose operations to prevent aerosol generation. Use HEPA filtered, externally vented, biosafety cabinet when preparing or handling this product.
Personal Protective Equipment	
Eye/face Protection	Wear safety glasses with side-shields.
Skin Protection	Wear double gloves or "chemotherapy" gloves. Immediately change gloves when torn, punctured, or contaminated. Wear closed-front, low-permeability protective gowns with tight-fitting wrist cuffs when working with this product.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	Avoid contact with skin, eyes and clothing. Conduct a task-specific risk assessment prior to authorizing work with this product. Wash hands and face before breaks and immediately after handling the product.
Other	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Biopharmaceutical liquid	Physical State	Liquid
Color	Various	Odor	Not available
Odor Threshold	Not available		
pH	8.5		
Specific Gravity	Not available	Water Solubility	Soluble in water
Solubility	Not available	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	Not available
Vapor Pressure	Not applicable		
Boiling Point	Not available	Autoignition Temperature	Not applicable
Flash Point	Not applicable	Method	None
Melting Point	Not applicable		
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Methotrexate	
LD50 Oral	180 - 317 mg/kg rats >2000 mg/kg rabbits
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Methotrexate	
No Toxicologic Effect Dose/Species/Study Length:	Methotrexate toxicity in animals was characterized by gastrointestinal hemorrhage, weakness, emesis, diarrhea, weight loss, bone marrow suppression, and liver damage.

Maximum Tolerated Dose (MTD), Oral

Methotrexate	
Carcinogenicity	Carcinogenicity studies in rats have been inconclusive. Signs of toxicity were related to characteristic bone marrow suppression and liver damage. The IARC group has evaluated Methotrexate for its carcinogenic potential and found inadequate evidence for Carcinogenicity in either humans or animals (Group 3).
Genetic Toxicity	AMES Test :Negative- Nonmutagenic Weakly positive in the mouse lymphoma assay, and positive in the cell transformation assay. It also induced chromosomal aberrations and increased the incidence of sister chromatid exchange. In vivo, it increased the incidences of polychromatic erythrocytes and chromosomal aberrations.
Reproductive Toxicity Developmental Toxicity	No data available Methotrexate induced teratogenic effects and embryoletality in several species, including humans, at doses that are non-toxic to the mother.

Methotrexate	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References	Product Profiles
Revision Summary	Change to OEG.

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