



NFPA	HMIS	PPE	Transport Symbol						
	<table border="1"> <tr> <td>Health Hazard</td> <td>2*</td> </tr> <tr> <td>Fire Hazard</td> <td>0</td> </tr> <tr> <td>Reactivity</td> <td>0</td> </tr> </table>	Health Hazard	2*	Fire Hazard	0	Reactivity	0		
Health Hazard	2*								
Fire Hazard	0								
Reactivity	0								

Issuing Date 26-Jan-2007

Revision Date 12-June-2007

Revision Number 1

\* Indicates a chronic health hazard.

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name** Methotrexate Injection, USP, 25 mg/mL

**Product Code(s)**  
 10139-062-02 – 2 mL Vial  
 10139-062-10 – 10 mL Vial  
 10139-062-40 – 40 mL Vial

**Recommended Use** Antineoplastic, Antimetabolite Agent

**Supplier Address**  
 GeneraMedix Inc.  
 150 Allen Road  
 Liberty Corner, New Jersey 07938, USA  
 TEL: 908-504-1300

**Chemical Emergency Phone Number** Chemtrec 1-800-424-9300

**2. HAZARDS IDENTIFICATION**

**WARNING!**

**Emergency Overview**

Harmful by inhalation, in contact with skin and if swallowed.  
 May cause skin, eye, and respiratory tract irritation.  
 May cause adverse cardiovascular effects.  
 May cause central nervous system depression.  
 May cause adverse liver effects.  
 May cause adverse kidney effects.  
 Contains a known or suspected mutagen.  
 Contains a known or suspected reproductive toxin.

**Appearance** Yellowish-orange

**Physical State** Liquid

**Odor** Odorless

**Potential Health Effects**

<b>Principle Routes of Exposure</b>	Inhalation, skin contact.
<b>Acute Toxicity</b>	
<b>Eyes</b>	May cause irritation.
<b>Skin</b>	May cause skin irritation and/or dermatitis.
<b>Inhalation</b>	Inhalation of vapors in high concentration may cause irritation of respiratory system. May cause additional effects as listed under "Ingestion".
<b>Ingestion</b>	Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause central nervous system depression. May cause adverse cardiac effects, blood disturbances, and metabolic acidosis. May cause adverse liver effects. May cause adverse kidney effects. May cause adverse effects on the bone marrow and blood-forming system.
<b>Chronic Effects</b>	Prolonged or repeated exposure increases the risk. Experiments have shown reproductive toxicity effects on laboratory animals.
<b>Aggravated Medical Conditions</b>	Liver disorders, kidney disorders, central nervous system, cardiovascular, blood disorders, and respiratory disorders. Overexposure may cause female and male reproductive disorder(s).
<b>Environmental Hazard</b>	See Section 12 for additional Ecological information.

<b>3. COMPOSITION/INFORMATION ON INGREDIENTS</b>
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Chemical Name	CAS-No	Weight %
Methotrexate	59-05-2	2.5
Sodium Chloride (NaCl)	7647-14-5	0.49
Water for Injection	7732-18-5	97

Sodium Hydroxide and Hydrochloric Acid for pH adjustment of 8.5.

<b>4. FIRST AID MEASURES</b>
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<b>General Advice</b>	Call 911 or emergency medical service. Remove and isolate contaminated clothing and shoes.
<b>Eye Contact</b>	In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
<b>Skin Contact</b>	For minor skin contact, avoid spreading material on unaffected skin.
<b>Inhalation</b>	Move victim to fresh air. Apply artificial respiration if victim is not breathing. Administer oxygen if breathing is difficult.
<b>Ingestion</b>	Call a physician or Poison Control Center immediately. Drink 1 or 2 glasses of water. Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice.
<b>Notes to Physician</b>	Keep victim warm and quiet. Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.
<b>Protection of First-aiders</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Do not use mouth-to-mouth method 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.

## 5. FIRE-FIGHTING MEASURES

<b>Flammable Properties</b>	Not flammable.
<b>Flash Point</b>	N/A .
<b>Suitable Extinguishing Media</b>	Dry chemical, CO <sub>2</sub> or water spray. Move containers from fire area if you can do it without risk. Dike fire control water for later disposal; do not scatter the material.

### Explosion Data

<b>Sensitivity to mechanical impact</b>	No data available.
<b>Sensitivity to static discharge</b>	No data available.

### **Specific Hazards Arising from the Chemical**

When heated, vapors may form explosive mixtures with air: indoors, outdoors, and sewers explosion hazards. Those substances designated with a "P" may polymerize explosively when heated or involved in a fire. Runoff may pollute waterways. Substance may be transported in a molten form.

### **Protective Equipment and Precautions for Firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

<b><u>NFPA</u></b>	<b>Health Hazard 2</b>	<b>Flammability 0</b>	<b>Stability 0</b>	<b>Physical and Chemical Hazards N/A</b>
<b><u>HMIS</u></b>	<b>Health Hazard 2*</b>	<b>Flammability 0</b>	<b>Stability 0</b>	<b>Personal Precautions B</b>

\* Indicates a chronic health hazard.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Stop leak if you can do it without risk.
<b>Methods for Containment</b>	Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers.
<b>Methods for Cleaning Up</b>	Soak up with inert absorbent material. Keep in suitable and closed containers for disposal.

## 7. HANDLING AND STORAGE

<b>Handling</b>	Wear personal protective equipment. Handle in accordance with good industrial hygiene and safety practice. Keep away from open flames, hot surfaces and sources of ignition.
<b>Storage</b>	Store locked up. Keep container tightly closed in a dry and well-ventilated place. Protect from light.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Exposure Guidelines</b>	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
<b>Engineering Measures</b>	Showers. Eyewash stations. Ventilation systems.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Safety glasses with side-shields.
<b>Skin and body protection</b>	Impervious gloves.
<b>Respiratory Protection</b>	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
<b>Hygiene Measures</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Yellowish-orange.	<b>Odor</b>	Odorless.
<b>Physical State</b>	Liquid.	<b>pH</b>	8.5
<b>Flash Point</b>	N/A.	<b>Autoignition Temperature</b>	N/A
<b>Boiling Point/Range</b>	>100°C / >212°F	<b>Melting Point/Range</b>	>185-204°C /265-399°F
<b>Flammability Limits in Air</b>	No data available.	<b>Specific Gravity</b>	1
<b>Solubility</b>	Insoluble in water.	<b>VOC Content</b>	N/A.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	Stable under recommended storage conditions.
<b>Conditions to Avoid</b>	Do not freeze. Protect from light.
<b>Incompatible Products</b>	Strong oxidizing agents. Strong acids.
<b>Hazardous Decomposition Products</b>	Carbon monoxide (CO), carbon dioxide (CO <sub>2</sub> ), nitrogen oxides (NO <sub>x</sub> ).
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur.

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

#### Product Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Methotrexate	135 mg/kg (rat) 146 mg/kg (mouse)	N/A	N/A
Sodium Chloride (NaCl)	3 g/kg (rat)	10 g/kg (rabbit)	42 g/m <sup>3</sup> (rat) 1 h

#### Subchronic Toxicity (28 days)

N/A

### Chronic Toxicity

#### Chronic Toxicity

Prolonged or repeated exposure increases the risk. Experiments have shown reproductive toxicity effects on laboratory animals.

#### Carcinogenicity

There are no known carcinogenic chemicals in this product.

### Mutagenicity

#### Mutagenic Effects

Animal experiments showed mutagenic and teratogenic effects.

#### Reproductive Toxicity

Crosses the placenta. Excreted in breast milk. May cause adverse reproductive effects, including testicular and ovarian damage, sperm abnormalities, menstrual disorders, fetotoxicity, embryotoxicity, and post-implantation mortality.

#### Teratogenic Effects

Possible risk of harm to the unborn child.

#### Target Organ Effects

Liver, kidney, respiratory system, skin, central nervous system (CNS), blood, gastrointestinal tract (GI), cardiovascular system, bone marrow, and reproductive system.

#### Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

## 13. DISPOSAL CONSIDERATIONS

#### Waste Disposal Method

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

#### Contaminated Packaging

Dispose of in accordance with local regulations.

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14. TRANSPORT INFORMATION
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<u>DOT</u>	Not regulated.
<u>TDG</u>	Not regulated.
<u>MEX</u>	Not regulated.
<u>ICAO</u>	Not regulated.
<u>IATA</u>	Not regulated.
<u>IMDG/IMO</u>	Not regulated.
<u>RID</u>	Not regulated.
<u>ADR</u>	Not regulated.
<u>ADN</u>	Not regulated.

## 15. REGULATORY INFORMATION

**International Inventories**

TSCA	Complies
DSL	Does not Comply
EINECS/ELINCS	Complies
ENCS	Does not Comply
CHINA	Does not Comply
KECL	Complies
PICCS	Does not Comply
AICS	Complies

**U.S. 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**

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

**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).

**U.S. State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Methotrexate	59-05-2	Developmental

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

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Methotrexate	X	X	N/A	N/A	N/A

**International Regulations**

Mexico - Grade Moderate risk, Grade 2

**Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR.

**WHMIS Hazard Class**

D2B Toxic materials



16. OTHER INFORMATION

Revision Date                      23-Feb-2007  
Revision Note                      NO DATA AVAILABLE

**Disclaimer**

The information provided on this MSDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

**End of MSDS**