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

Product Name: Methotrexate Sodium Tablets
Common Name: Not available
Chemical Name: Not applicable
Synonyms: Rheumatrex, 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

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>EC No.</th>
<th>Composition</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methotrexate</td>
<td>59-05-2</td>
<td>2004138</td>
<td>2.5 - 10 mg/tablet</td>
<td>T, Xi; R23/24/25, 40, 46, 61; S45, 53</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

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

Appearance: Pharmaceutical Tablet or Capsule
Physical State: Solid
Odor: Not available

Potential Physical Hazards: Powders and solids are presumed to be combustible.

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**  
  Use water spray, foam, dry chemical or carbon dioxide.
- **Unsuitable Extinguishing Media**  
  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

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Exposure Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methotrexate</td>
<td>0.1 mcg/m³</td>
</tr>
</tbody>
</table>

**Engineering Controls**

Enclose operations to prevent aerosol generation. Use HEPA filtered, externally vented, biosafety cabinet when preparing or handling this product.

**Personal Protective Equipment**

<table>
<thead>
<tr>
<th>Eye/face Protection</th>
<th>Skin Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear safety glasses with side-shields.</td>
<td>Wear double gloves or &quot;chemotherapy&quot; 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.</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical State</th>
<th>Color</th>
<th>Odor Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Tablet or Capsule</td>
<td>Solid</td>
<td>Various</td>
<td>Not available</td>
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</table>

<table>
<thead>
<tr>
<th>pH</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific Gravity</th>
<th>Water Solubility</th>
<th>Solubility</th>
<th>Evaporation Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Insoluble in water</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partition Coefficient (n-octanol/water)</th>
<th>Vapor Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available</td>
<td>Not applicable</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Vapor Pressure</th>
<th>Autoignition Temperature Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boiling Point</th>
<th>Autoignition Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flash Point</th>
<th>Autoignition Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Melting Point</th>
<th>Autoignition Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available</td>
<td>Not applicable</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Flammability Limits in Air</th>
<th>Autoignition Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Explosion Limits</th>
<th>Autoignition Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Upper</th>
<th>Lower</th>
<th>Autoignition Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Chemical Stability</th>
<th>Conditions to Avoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable at room temperature.</td>
<td>No data available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Materials to Avoid</th>
<th>Hazardous Decomposition Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>No materials to be especially mentioned.</td>
<td>None under normal use.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Possibility of Hazardous Reactions</th>
<th></th>
</tr>
</thead>
</table>
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 No data available
Developmental Toxicity Methotrexate induced teratogenic effects and embryolethality 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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End of MSDS