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

Product Name  Mylotarg
Common Name  Not available
Chemical Name  Not applicable
Synonyms  Not available
Product Use  Pharmaceutical product
Classification  Antineoplastic Agent
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>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Remainder</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Gemtuzumab Ozogamicin</td>
<td>220578-59-6</td>
<td>None assigned</td>
<td>5 mg/vial</td>
<td>R36, S36/37/39/51</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 powder
Physical State  Solid
Odor  Not available

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

Potential Health Effects

<table>
<thead>
<tr>
<th>Eyes</th>
<th>May cause mechanical eye irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Not available</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Not available</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Not available</td>
</tr>
<tr>
<td>Other</td>
<td>The most common effects may include myelosuppression, hypersensitivity reactions, mucositis, pruritus, abdominal pain, asthenia/weakness, back pain, chills, fever, headache, infection, neutropenic fever, pain, sepsis, hemorrhage, hypertension, hypotension, tachycardia, anorexia, constipation, diarrhea, dyspepsia, gum hemorrhage, nausea, stomatitis, vomiting, anemia, ecchymosis, leukopenia, petechiae, thrombocytopenia, hyperglycemia, hypocalcemia, hypokalemia, peripheral edema, myalgia, anxiety, depression, dizziness, insomnia, cough increase, dyspnea, epistaxis, pharyngitis, pneumonia, pulmonary effects, rhinitis, Herpes simplex, rash, metrorrhagia, and vaginal hemorrhage.</td>
</tr>
</tbody>
</table>
Possible development of severe hypersensitivity reactions (including Anaphylaxis) which may include severe pulmonary events. Immunosuppressent. Hepatotoxicity, including severe veno-occlusive disease, has been reported with product use.

May cause harm to the unborn child. May be excreted in breast milk.

Please see Patient Package Insert for further information.

**Therapeutic Target Organ(s)**
Liver, Bone Marrow, Kidneys.

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.

**Other**
Participate in a medical surveillance program if working directly with this product.

### 5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Not flammable

**Extinguishing Media**

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Unsuitable Extinguishing Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use water spray, foam, dry chemical or carbon dioxide.</td>
<td>Do NOT use water jet.</td>
</tr>
</tbody>
</table>

**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: Gemtuzumab Ozogamicin
Exposure Guideline: 2 mcg/m³

Engineering Controls
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. Consult a health and safety professional for specific PPE, respirator and risk assessment guidance.

Other
Limit access to only personnel trained in the safe handling of this material.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical powder</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temperature Method</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Method</td>
<td>None</td>
</tr>
<tr>
<td>Upper</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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

Gemtuzumab Ozogamicin
LD50 Oral 1175 mg/kg rats
Acute Dermal Irritation Not applicable
Primary Eye Irritation Not applicable
Sensitization Not applicable

Multiple Dose Toxicity

Gemtuzumab Ozogamicin
No Toxicologic Effect
Dose/Species/Study Length: The acute and chronic toxicity has been evaluated in rats and monkeys. Signs of toxicity included decreased body weight and food consumption, bone marrow toxicity, and liver and kidney effects. Target organs that were affected were kidneys, liver, bone marrow, lymphoid tissues, and male reproduction organs. In rats, the male mammary gland was also a target organ.

Maximum Tolerated Dose (MTD), Oral

Gemtuzumab Ozogamicin
Carcinogenicity Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
Genetic Toxicity Positive in the mouse micronucleus assay.
Reproductive Toxicity Studies were found to adversely affect male, but not female, fertility in rats causing decreased sperm counts, sperm mobility, hypospermia, decreased reproductive organ weights, testicular tubular degeneration, and prostate atrophy.
Developmental Toxicity At maternally toxic doses in rats, it was embryo/fetotoxic and caused reduced pup survival. There was also an increased incidence of skeletal system anomalies in the fetuses.

Gemtuzumab Ozogamicin
Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

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

See Patient Package Insert for more information.

Revision Summary

Not applicable

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End of MSDS