# Safety Data Sheet
## European Format

## Mylotarg

**Preparation Date** 29-Aug-2007 **Revision Date** 09-Sep-2008 **Revision Number** 2

## 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

| Common Name | CAS-No | EC No. | Composition | Classification |
|---|---|---|---|---|
| Inactive Ingredients | Not applicable | Not applicable | Remainder | Not applicable |
| Gemtuzumab Ozogamicin | 220578-59-6 | None assigned | 5 mg/vial | R36, S36/37/39/51 |

## 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**

**Eyes** May cause mechanical eye irritation.
**Skin** Not available
**Inhalation** Not available
**Ingestion** Not available
**Other** 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.

| | |
|---|---|
| | 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.<br><br>May cause harm to the unborn child. May be excreted in breast milk.<br><br>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** | |
| **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

| **Common Name** | **Exposure Guideline** |
|---|---|
| Gemtuzumab Ozogamicin | 2 mcg/$m^3$ |

**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-specifc 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

| | | | |
|---|---|---|---|
| **Appearance** | Pharmaceutical powder | **Physical State** | Solid |
| **Color** | White | **Odor** | Not available |
| **Odor Threshold** | Not available | | |
| **pH** | Not applicable | | |
| **Specific Gravity** | Not applicable | **Water Solubility** | Not available |
| **Solubility** | Not applicable | **Evaporation Rate** | Not applicable |
| **Partition Coefficient (n-octanol/water)** | Not available | **Vapor Pressure** | Not applicable |
| **Boiling Point** | Not applicable | **Autoignition Temperature** | Not applicable |
| **Flash Point** | Not applicable | **Method** | None |
| **Melting Point** | Not available | | |
| **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**

**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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