SAFETY DATA SHEET

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

Product Identifier

Material Name: Gemtuzumab Ozogamicin

Trade Name: Mylotarg

Compound Number: PF-05208747; CMA-676

Synonyms: Gemtuzumab Ozogamicin for Injection

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
- Germ Cell Mutagenicity: Category 2
- Reproductive Toxicity: Category 1B
- Specific target organ systemic toxicity (repeated exposure): Category 2

US OSHA Specific - Classification
- Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger

Hazard Statements:
- H341 - Suspected of causing genetic defects
- H373 - May cause damage to organs through prolonged or repeated exposure
- H360FD - May damage fertility. May damage the unborn child. May form combustible dust concentrations in air

Precautionary Statements:
- P201 - Obtain special instructions before use
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray
- P281 - Use personal protective equipment as required
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P405 - Store locked up

Emergency telephone number:
- International CHEMTREC (24 hours): +1-703-527-3887
- CHEMTREC (24 hours): 1-800-424-9300
- Pfizer Ltd Emergency telephone number: +00 44 (0)1304 616161

Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Global Supply
Pfizer Inc
235 East 42nd Street
New York, NY 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

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SAFETY DATA SHEET

Material Name: Gemtuzumab Ozogamicin
Revision date: 20-Mar-2019

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemtuzumab Ozogamicin</td>
<td>220578-59-6</td>
<td>Not Listed</td>
<td>Repr.1B (H360FD) Muta.2 (H341) STOT RE.2 (H373)</td>
<td>1-5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextran</td>
<td>9004-54-0</td>
<td>232-677-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>SODIUM CHLORIDE</td>
<td>7647-14-5</td>
<td>231-598-3</td>
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<tr>
<td>Sodium phosphate, dibasic</td>
<td>7558-79-4</td>
<td>231-448-7</td>
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<td>*</td>
</tr>
<tr>
<td>Sodium Phosphate Monobasic, Monohydrate</td>
<td>10049-21-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Restrict access to work area. Ground and bond all bulk transfer equipment. Minimize dust generation. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate ‘good laboratory/manufacturing’ decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product used as Antineoplastic
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

### Sucrose

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

### SODIUM CHLORIDE

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

**Gemtuzumab Ozogamicin**

- **Pfizer Occupational Exposure Band (OEB):**
  - B-OEB 5 (control exposure to <10 μg/day)

**SODIUM CHLORIDE**

- **Pfizer Occupational Exposure Band (OEB):**
  - OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

**Sodium phosphate, dibasic**

- **Pfizer Occupational Exposure Band (OEB):**
  - OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all large scale operations should be fully enclosed. Air recirculation is not recommended.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eyes: Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Powder or cake</th>
<th>Color:</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Sucrose
No data available

SODIUM CHLORIDE
No data available

Sodium phosphate, dibasic
No data available

Gemtuzumab Ozogamicin
No data available

Dextran
No data available

Sodium Phosphate Monobasic, Monohydrate
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

<table>
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<tr>
<th>Autoignition Temperature (Solid) (°C):</th>
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</thead>
<tbody>
<tr>
<td>Flammability (Solids):</td>
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</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
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</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity: No data available
10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following intravenous exposure to this compound may include: changes in blood cell levels, vomiting, fever, chills, and nausea.

Acute Toxicity: (Species, Route, End Point, Dose)

Sucrose
Rat Oral LD 50 29,700 mg/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

Gemtuzumab Ozogamicin
Rat Intravenous Non-Lethal Dose 9.8 mg protein/m²
Non-human Primate IV Non-Lethal Dose 36.9mg protein/m²

Dextran
Rat Oral LD50 > 3000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Gemtuzumab Ozogamicin
6 Week(s) Rat Intravenous 2.8 mg protein/m²/wk LOAEL Liver, Kidney, Male reproductive system, Bone marrow
6 Week(s) Monkey Intravenous 7.38 mg protein/m²/wk LOAEL Thymus, Liver, Kidney, Lymphoid tissue

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

Gemtuzumab Ozogamicin
Reproductive & Fertility-Males  Rat  Intravenous  0.112 mg protein/m²/day  LOAEL  Fertility
Reproductive & Fertility - Females  Rat  Intravenous  0.348 mg protein/m²/day  LOAEL  Maternal Toxicity, Embryotoxicity
Reproductive & Fertility-Females  Rat  Intravenous  1.04 mg protein/m²/day  NOAEL  Fertility
Embryo / Fetal Development  Rat  Intravenous  0.059 mg protein/m²/day  LOAEL  Maternal Toxicity, Fetotoxicity, Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Gemtuzumab Ozogamicin
In Vivo Micronucleus  Rat Bone Marrow  Positive

Carcinogen Status:  Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

Toxicity:  No data available

Persistence and Degradability:  No data available

Bio-accumulative Potential:  No data available

Mobility in Soil:  No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:  Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemtuzumab Ozogamicin</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Dextran</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>EU EINECS/ELINCS List</td>
<td>232-677-5</td>
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<tr>
<td>Sucrose</td>
<td>Not Listed</td>
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<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<tr>
<td>SODIUM CHLORIDE</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>EU EINECS/ELINCS List</td>
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<td>Sodium phosphate, dibasic</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>EU EINECS/ELINCS List</td>
<td>231-598-3</td>
</tr>
<tr>
<td>Sodium Phosphate Monobasic, Monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**EU EINECS/ELINCS List**

- Gemtuzumab Ozogamicin: 200-334-9
- Dextran: 232-677-5
- Sodium Phosphate Monobasic, Monohydrate: Not Listed

**CERCLA/SARA Hazardous Substances and their Reportable Quantities:**

- Sodium phosphate, dibasic:
  - 5000 lb
  - 2270 kg

**California Proposition 65**

- Inventory - United States TSCA - Sect. 8(b)
  - Present
  - Australia (AICS): Present
  - EU EINECS/ELINCS List: 231-448-7

**Inventory - United States TSCA - Sect. 8(b)**

- Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-448-7

**California Proposition 65**

- Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-448-7
16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.
Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 20-Mar-2019

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet