Standard Operating Procedure

**Gemtuzumab ozogamicin**

*This is an SOP template and is not complete until: 1) lab specific information is entered into the box below 2) lab specific protocol/procedure is added to the protocol/procedure section and
3) SOP has been signed and dated by the PI and relevant lab personnel.*

 Print a copy and insert into your
*Laboratory Safety Manual* and *Chemical Hygiene Plan*.
Refer to instructions for assistance.

|  |  |
| --- | --- |
| **Department:** | Click here to enter text. |
| **Date SOP was written:** | Click here to enter a date. |
| **Date SOP was approved by PI/lab supervisor:** | Click here to enter a date. |
| **Principal Investigator:** | Click here to enter text. |
| **Internal Lab Safety Coordinator/Lab Manager:** | Click here to enter text. |
| **Lab Phone:** | Click here to enter text. |
| **Office Phone:** | Click here to enter text. |
| **Emergency Contact:** | Click here to enter text. |
| *(Name and Phone Number)* |
| **Location(s) covered by this SOP:** | Click here to enter text. |
| *(Building/Room Number)* |

**Type of SOP:** ☐ Process ☒Hazardous Chemical ☐ Hazardous Class

**Purpose**

Gemtuzumab ozogamicin (trade name Mylotarg) may be harmful if inhaled, ingested, or absorbed through the skin. It may cause irritation to the gastrointestinal tract, respiratory tract, skin, and eyes. Gemtuzumab ozogamicin is a monoclonal antibody conjugated with an antitumor antibiotic that binds specifically to the CD33 antigen. It was used to treat acute myeloid leukemia. The FDA withdrew the drug from the market in 2010 when clinical trials showed that the drug increased patient death and demonstrated no benefit over traditional chemotherapies.

**Physical & Chemical Properties/Definition of Chemical Group**

CAS#: 220578-59-6

Class: **NIOSH Hazardous Antineoplastic Agent**

Molecular Formula: Unspecified

Form (physical state): Solid

Color: White

Boiling point: Unknown

**Potential Hazards/Toxicity**

Gemtuzumab ozogamicin may be harmful if inhaled, ingested, or absorbed through the skin. It may cause irritation to the gastrointestinal tract, respiratory tract, skin, and eyes. Symptoms of exposure include myelosuppression, hypersensitivity, mucositis, abdominal pain, weakness, back pain, chills, fever, headache, infection, pain, sepsis, hemorrhage, hypertension, hypotension, tachycardia, anorexia, constipation, diarrhea, dyspepsia, nausea, stomatitis, vomiting, anemia, leukopenia, thrombocytopenia, hyperglycemia, hypocalcemia, edema, myalgia, anxiety, depression, dizziness, insomnia, coughing, dyspnea, pharyngitis, pneumonia, pulmonary effects, rhinitis, and rash. The toxicological properties have not been fully investigated. It is listed in NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012.

**Personal Protective Equipment (PPE)**

**Respirator Protection**.

Lab personnel intending to use/wear a respirator mask must be trained and fit-tested by ORS and should contact occhealt@uga.edu. This is a UGA requirement described in more detail in the [UGA Respiratory Protection Plan](https://esd.uga.edu/sites/default/files/respiratoryprotection.pdf) and supported by the [Office of Research Occupational Health and Safety Program](https://research.uga.edu/ohsp/).

Respirators should be used only under any of the following circumstances:

* As a last line of defense (i.e., after engineering and administrative controls have been exhausted).
* When Permissible Exposure Limit (PEL) has exceeded or when there is a possibility that PEL will be exceeded.
* Regulations require the use of a respirator.
* An employer requires the use of a respirator.
* There is potential for harmful exposure due to an atmospheric contaminant (in the absence of PEL).
* As PPE in the event of a chemical spill clean-up process.

**Hand Protection**

Handle with nitrile or chloroprene gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

NOTE: Consult with your preferred glove manufacturer to ensure that the gloves you plan on using are compatible with gemtuzumab ozogamicin.

Refer to glove selection chart from the links below:

<http://www.ansellpro.com/download/Ansell_8thEditionChemicalResistanceGuide.pdf>

OR

<http://www.showabestglove.com/site/default.aspx>

OR

<http://www.mapaglove.com/>

**Eye Protection**

ANSI approved safety glasses or goggles.

**Skin and Body Protection**

Lab coats should be worn. These laboratory coats must be appropriately sized for the individual and be buttoned to their full length. Laboratory coat sleeves must be of a sufficient length to prevent skin exposure while wearing gloves. Full length pants and close-toed shoes must be worn at all times by all individuals that are occupying the laboratory area. The area of skin between the shoe and ankle should not be exposed.

**Hygiene Measures**

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

**Engineering Controls**

Work with this chemical in a certified ducted fume hood. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

**First Aid Procedures**

**If inhaled**

Move person into fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Consult a physician.

**In case of skin contact**

Wash off with soap and plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Consult a physician.

**In case of eye contact**

Flush with plenty of water for at least 15 minutes lifting upper and lower eyelids and removing contact lenses. Consult a physician.

**If swallowed**

Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

**Special Handling and Storage Requirements**

**Precautions for safe handling:** Avoid contact with skin and eyes. Avoid inhalation and ingestion. Avoid dust formation. Ensure normal measures for preventive fire protection.

**Conditions for safe storage:** Keep containers tightly closed in a dry, cool, and well-ventilated place.

**Spill and Accident Procedure**

**Chemical Spill Dial 911**

**24-7 On-Call Response to Research, Environment, Health or Safety Concerns Dial 2-5561 from a campus phone or 706-542-5561 from a non-campus line.**

**Spill** – Follow the procedures set out in the [UGA Chemical and Laboratory Safety Manual.](http://research.uga.edu/docs/units/safety/manuals/Chemical-Laboratory-Safety-Manual.pdf)

[If there are any chemical-specific protocols for responding to a spill, insert them here or mark “none”:]

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# **Medical Emergency Dial 911**

**Life Threatening Emergency, After Hours, Weekends And Holidays** – Dial **911** or the emergency phone numbers listed at the beginning of the UGA Chemical and Laboratory Safety Manual

*Note: All incidents that result in an injury or property damage must be reported to ORS / ESD using a University Incident/Accident Report.*

**Non-Life Threatening Emergency** – Follow the instructions in the UGA Chemical and Laboratory Safety Manual.

*Note: All incidents that result in an injury or property damage must be reported to ORS / ESD using a University Incident/Accident Report.*

**Decontamination/Waste Disposal Procedure**

**For general hazardous waste disposal procedures, see Appendix H of the UGA Chemical and Laboratory Safety Manual.**

**Chemical Specific Procedures: [to be inserted or marked as “none”]**

Wearing proper PPE, decontaminate equipment and bench tops using soap and water. Dispose of the used gemtuzumab ozogamicin and disposables contaminated with gemtuzumab ozogamicin as hazardous waste.

**Safety Data Sheet (SDS) Location**

UGA personnel can access Online SDS through a link in the upper left corner of the ESD home page (<https://esd.uga.edu>) and logging in by using their UGA email user name and password.

**Protocol/Procedure (Add lab specific Protocol/Procedure here)**

Click here to enter text.

**NOTE**

Any deviation from this SOP requires approval from PI.

**Documentation of Training** (signature of all users is required)

* Prior to conducting any work with gemtuzumab ozogamicin, designated personnel must provide training to his/her laboratory personnel specific to the hazards involved in working with this substance, work area decontamination, and emergency procedures.
* The Principal Investigator must provide his/her laboratory personnel with a copy of this SOP and access to the SDS provided by the manufacturer.
* The Principal Investigator must ensure that his/her laboratory personnel have attended appropriate laboratory safety training or refresher training within the last 12 months.

**Principal Investigator**

Print name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approval Date:

I have read and understand the content of this SOP:

|  |  |  |
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| **Name** | **Signature** | **Date** |
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