1. **Product and Company Identification**

   **Manufactured/Supplied by**
   MERCK & CO., INC.
   One Merck Drive
   Whitehouse Station, NJ 08889-0100
   (908) 423-1000

   **Emergency Telephone Number:** 1-732-594-5555

   **Label Name**
   MUSTARGEN®

   **Chemical Name**
   Mechlorethamine HCl: 2-Chloro-N-(2-chloroethyl)-N-methylethanamine hydrochloride
   Mechlorethamine Hydrochloride; HN2 Hydrochloride; Trituration of MUSTARGEN®

   **Material Product Number**
   7753; **NDC #** 0006-7753-31

   **Intended Use**
   Antineoplastic nitrogen mustard agent.

2. **Composition/Information on Ingredients**

<table>
<thead>
<tr>
<th>Component</th>
<th>Molecular Formula</th>
<th>Molecular weight</th>
<th>CAS Number</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MECHLORETHAMINE HYDROCHLORIDE</td>
<td>C5H11Cl2N·HCl</td>
<td>192.52</td>
<td>55-86-7</td>
<td>9</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>NaCl</td>
<td>58.44</td>
<td>7647-14-5</td>
<td>91</td>
</tr>
</tbody>
</table>

   **EC Label**
   Very toxic
   R34- Causes burns.
   R45- May cause cancer.
   R46- May cause heritable genetic damage.
   R48/26/28- Very toxic: Danger of serious damage to health by prolong exposure by inhalation and if swallowed.
   R61- May cause harm to the unborn child.

3. **Hazards Identification**

   **Appearance**
   Light yellow brown crystalline hygroscopic powder.

   **Label Text**
   DANGER!
   FINISHED PHARMACEUTICAL PRODUCT.
   CYTOTOXIC ANTI Giám PLASTIC AGENT.
   HIGHLY TOXIC IF SWALLOWED OR INHALED.
   CAUSES EYE AND SKIN BURNS.
   HIGHLY IRRITATING TO THE RESPIRATORY TRACT.
   CAUSES BONE MARROW SUPPRESSION.
   CAN CAUSE BIRTH DEFECTS.
   CAN CAUSE HERITABLE GENETIC EFFECTS.
   CAN CAUSE CANCER.

*** Continued on next page ***
4. **First Aid Measures**

**Eye Contact**

Should accidental eye contact occur, copious irrigation for at least 15 minutes with water, normal saline or a balanced salt ophthalmic irrigating solution should be instituted immediately. Get medical attention immediately, followed by prompt ophthalmologic consultation.

**Skin Contact**

In case of contact, irrigate with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. Then wash with 2% solution of sodium thiosulfate. Do not use organic solvents to cleanse skin. Destroy contaminated clothing. Get medical attention immediately.

**Inhalation**

**Note to First Aid Responders:** Prior to removing to fresh air, rescuers need respiratory protection, eye protection and gloves. See Section 8 for Personal Protective Equipment.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

**Ingestion**

Do not induce vomiting. May dilute with water, then get medical attention immediately.

**Notes to physician**

MECHLORETHAMINE HYDROCHLORIDE: No known antidote. Treatment should consist of symptomatic and supportive care.

5. **Fire Fighting Measures**

**Flash Point**

Not applicable.

**Flammable Limits (% in air)**

Not applicable.

**Autoignition Temperature**

Not available.

**Oxidizing Properties**

Not available.

**Combustibility Information**

Not available.

**Dust Explosivity Information**

Not available.

**Shock Sensitivity**

No.

**Fire/Explosion Hazards**

MECHLORETHAMINE HYDROCHLORIDE: Dangerous when heated to decomposition; emits highly toxic fumes containing chlorides and NO2.

**Special Fire Procedures**

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear if vials are involved in fire and contents are released or burning.
6. Accidental Release Measures

**Personal Precautions**
Immediately contact emergency personnel. Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

**Methods for cleaning up**
If emergency personnel are unavailable vacuum or carefully scoop up spilled materials and place in an appropriate container for disposal. Avoid creating dusty conditions and prevent wind dispersal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. See Section 13 for Waste Disposal Information.

Incineration is the preferred method of disposal. Small amounts can be neutralized as described below. To clean non-disposable equipment, glassware, gloves, tubing, etc., soak in an aqueous solution containing equal volumes of sodium thiosulfate (5%) and sodium bicarbonate (5%) for 45 minutes.

For additional assistance in the U.S., CHEMTREC provides a toll-free Hotline for chemical emergencies regarding spills, leaks, exposure or accidents: 1-800-424-9300.
For emergency calls from outside the U.S.: 1-703-527-3887

7. Handling and Storage

**Handling**
Appropriate protective equipment should be worn when handling MUSTARGEN. Avoid contact with eyes, skin and clothing. Do not ingest. Wash thoroughly after handling.

No special handling procedures for UNOPENED vials. Due to the drug's toxic and mutagenic properties, appropriate precautions including the use of appropriate safety equipment are recommended for the preparation of MUSTARGEN. The National Institute of Health presently recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II biological safety cabinet (BSC) and that personnel preparing drugs of this class should wear surgical gloves and a closed front surgical-type gown with knit cuffs.

It is preferable that material be handled in dissolved state. Confine any operation so that spilled or released material does not affect unprotected workers. Emphasize control by containment.

**Storage**
In the absence of specific storage recommendations, keep container in a cool, well-ventilated area. Keep container tightly closed.

*** Continued on next page ***
8. Exposure Controls/Personal Protection

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA Permissible Exposure Limit (PEL)</th>
<th>ACGIH Threshold Limit Value (TLV)</th>
<th>Merck Exposure Control Limit (ECL) or PB-ECL Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>MECHLORETHAMINE HYDROCHLORIDE</td>
<td>Not established</td>
<td>Not established</td>
<td>0.05 µg/m³ (8-hr TWA)</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>Not established</td>
<td>Not established</td>
<td>Not established</td>
</tr>
</tbody>
</table>

ADI = 0.5 µg/day PB-ECL
Wipe Test Criteria = 0.5 µg/100 cm²

A containment-oriented approach should be used to maintain potential exposure levels as low as possible, and preferably non-detectable, below recommended limits.

Analytical methods should be sensitive enough to detect the compound at or below these values.

Engineering Controls

Ventilation is not necessary if material is contained in a vial. Vials should be reconstituted in a Class II biological safety cabinet (BSC).

Personal Protective Equipment

Eye/Face Protection

Appropriate eye protective equipment should be worn when handling MUSTARGEN, i.e., splash goggles, face shield, or other full-face protection if potential exists for direct exposure.

Skin Protection

Use surgical (or chemo) latex or PVC gloves when handling or reconstituting vials. Double gloving is recommended. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Appropriate techniques should be used to remove potentially contaminated clothing.

Respiratory Protection

No respiratory protection required when handling sealed vials. As an adjunct to engineering controls, use an approved, properly fitted, powered-air purifying respirator, or respirator of equivalent or greater protection if the potential exists for exposure to airborne aerosols.

Additional Protective Equipment

None required when handling sealed vials. Disposable work uniform, preferably made of Tyvek or a closed front surgical-type gown with knit cuffs, is recommended for protection against aerosols.

9. Physical and Chemical Properties

Appearance

Light yellow brown crystalline hygroscopic powder.

Odor/Threshold Limit

MECHLORETHAMINE HYDROCHLORIDE: Faint fishy odor

pH

Neutral.

Boiling Point

Not applicable.

Melting Point

108 to 111°C (226.4 to 231.8°F)

Flash point

Not applicable.

Flammable Limits (% in air)

Not applicable.

*** Continued on next page ***
MUSTARGEN®

Autoignition Temperature: Not available.
Partition Coefficient: MECHLORETHAMINE HYDROCHLORIDE: Log Kow: 0.91

10. Stability and Reactivity
Stability: The product is stable.
Conditions to Avoid: MECHLORETHAMINE HYDROCHLORIDE: Hygroscopic. Avoid neutral or alkaline aqueous solutions.
Incompatibility: MECHLORETHAMINE HYDROCHLORIDE: Strong oxidizing agents.

11. Toxicological Information
Routes of Entry:
- Ingestion: Yes.
- Inhalation: Yes.
- Skin Contact: Yes.

Toxicity Data

<table>
<thead>
<tr>
<th>Component</th>
<th>Test</th>
<th>Species</th>
<th>Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUSTARGEN</td>
<td>LD50</td>
<td>Rat</td>
<td>I.V.</td>
<td>1.6 mg/kg</td>
</tr>
<tr>
<td>MECHLORETHAMINE</td>
<td>LD50</td>
<td>Mouse</td>
<td>I.V.</td>
<td>2 mg/kg</td>
</tr>
<tr>
<td>HYDROCHLORIDE</td>
<td>LD50</td>
<td>Rabbit</td>
<td>Oral</td>
<td>12.5 mg/kg</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>LD50</td>
<td>Rat</td>
<td>Oral</td>
<td>3000 mg/kg</td>
</tr>
</tbody>
</table>

Effects of Acute Exposure

Eye contact: No data are available on the formulated product. Mechlorethamine hydrochloride, the active ingredient, has been shown to be corrosive to the eyes in animal studies.

Skin contact: No data are available on the formulated product. Mechlorethamine hydrochloride, the active ingredient, is corrosive to the skin. The reconstituted drug is irritating to the skin.

Inhalation: No data are available on the formulated product. Mechlorethamine hydrochloride, the active ingredient, has been shown to be highly irritating to the mucous membranes of the respiratory tract.

*** Continued on next page ***
Ingestion

Not a normal route of administration; therefore there are no data available by this route in humans. Acute animal data indicate that the active ingredient, mechlorethamine hydrochloride, is very toxic by ingestion and may be irritating to the upper GI tract.

Effects of Chronic Exposure

**MECHLORETHAMINE HYDROCHLORIDE**: The compound is an alkylating agent that is cytotoxic to proliferating cells. It has been shown to cause genetic damage in a variety of genotoxicity tests. It was embryotoxic, teratogenic and impaired fertility in animal studies. It was also carcinogenic in mice and rats when administered by subcutaneous (SC), intraperitoneal (IP) or intravenous (IV) injection. Bone marrow suppression and toxic effects on the GI tract were produced with repeated IP or IV administration in animals.

In clinical use, IV administration in cancer patients produces bone marrow depression, nausea, vomiting, infertility and secondary malignancies. Hypersensitivity reactions, including anaphylaxis, have been reported.

Carcinogen Designation

**MECHLORETHAMINE HYDROCHLORIDE**: Listed as a carcinogen by IARC (2A), NTP.

Medical Conditions Aggravated by Overexposure:

**MECHLORETHAMINE HYDROCHLORIDE**: Pre-existing kidney, bone marrow, GI, liver or neurological dysfunction, infertility and pregnancy.

12. Ecological Information

Environmental Effects

Not available.

Ecotoxicity Data

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Period</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>MECHLORETHAMINE HYDROCHLORIDE</td>
<td>Not available.</td>
<td>Not available.</td>
<td>Not available.</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
<td>Not available.</td>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

Environmental Fate

**MECHLORETHAMINE HYDROCHLORIDE**: Mechlorethamine hydrochloride has an estimated Koc of 74 that suggests high mobility in soil. The compound hydrolyzes rapidly in water and moist soil. If released to the atmosphere, the compound has an estimated half-life of about two days. The log Kow of 0.91 suggests that the compound will not bind to sediment and will not bioaccumulate.
13. Disposal Considerations

Waste Disposal Information

Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spill residues including contaminated soils following all applicable regulations.

Incineration is the preferred method of disposal. Small amounts can be neutralized as described below. To clean non-disposable equipment, glassware, gloves, tubing, etc., soak in an aqueous solution containing equal volumes of sodium thiosulfate (5%) and sodium bicarbonate (5%) for 45 minutes.

14. Transport Information

Shipping Description

U.S. DOT

(Please note this material is shipped as toxic solids, organic-excepted small quantity. See 49CFR 173.4 (a)).

IATA/ICAO

Consumer Commodity, 9, ID8000

IMO

UN 3249 Medicine, Solid, Toxic N.O.S. (Mechlorethamine Hydrochloride mixture),6.1, III Limited Quantity.

Please note UN specification packaging hazard labels are not required. Package must be marked "Dangerous Good in limited quantities of Class 6."

ADR/RID

Not regulated

15. Regulatory Information

U.S. Federal Regulations


State Regulations

Not available.

International Regulations

Exempt from the EU Dangerous Substances Directive.

16. Other Information

Revisions: EC Label

Revision: 10/12/2007.

MSDS Coordinator:

1-908-423-7903

Merck & Co., Inc.

Two Merck Drive

P.O. Box 200, WS2W-13

Whitehouse Station, NJ 08889-0200

U.S.A.

Disclaimer:

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.