

# MATERIAL SAFETY DATA SHEET

PRODUCT NAME: MUSTARGEN  
PLANT MSDS CODE: MHHD-023

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Date: 8/2000

## 1. Chemical Product and Company Identification

Manufacturer----- U.S. HUMAN HEALTH  
A Division of Merck & Co., Inc.  
P.O. Box 4  
West Point, PA 19486

Emergency Telephone Number--- 1-800-NSC-MERCK (1-800-672-6372)  
Merck National Service Center (MNSC)

Chemical Name----- 2-Chloro-N-(2-chloroethyl)-N-  
methylethanamine hydrochloride

Synonyms (Common)----- MUSTARGEN  
(Chemical)----- HN<sub>2</sub>Hydrochloride; Nitrogen mustard;  
Mechlorethamine hydrochloride

Material Statistical Number-- 7753

Material Product Number----- Not available

Intended Use----- Antineoplastic agent

NDC Number----- 0006-7753-31

## 2. Composition/Information on Ingredients

| <u>Component</u>    | <u>Molecular Formula</u>                             | <u>Molecular Weight</u> | <u>CAS Number</u> | <u>Percent (%)</u> |
|---------------------|--|-------------------------|-------------------|--------------------|
| Mechlorethamine HCL | C <sub>5</sub> H <sub>11</sub> Cl <sub>2</sub> N.HCl | 192.52                  | 55-86-7           | 9                  |
| Sodium chloride     | ClNa   | 58.45                   | 7647-14-5         | 91                 |

EC Label----- C, R34, T+, R41

## 3. Hazards Identification

Appearance----- White or light yellow/brown crystalline  
hygroscopic powder, typically 10 mg of  
lyophilized powder in a small bottle to  
be reconstituted with injectable water.

Emergency Overview----- DANGER!  
Causes burns.  
Risk of serious damage to eyes.

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Potential Health Effects----- Corrosive to eyes and skin. Causes blisters to the skin. Highly irritating to the respiratory tract. Potentially irritating to the upper GI tract.

#### 4. First-Aid Measures

Eye Contact----- In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.

Skin Contact----- Wash with copious amounts of water for at least 15 minutes followed by a solution of 5% sodium thiosulfate. Do not use organic solvents to cleanse skin.

Inhalation----- Get to fresh air; maintain airway and get medical attention if necessary.

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

Notes to Physician----- No known antidote. Treatment should consist of symptomatic and supportive care.

#### 5. Fire-Fighting Measures

Flash Point (°C/°F)----- Not applicable

Flash Point Test Method----- Not applicable

Autoignition Temperature (°C/°F)-- Not available

Flammable Limits -LEL (%)---- Not applicable  
-UEL (%)---- Not applicable

Combustibility Information--- Not available

Dust Explosivity Information- Not available

Shock Sensitivity Information-- Not available

Extinguishing Media----- Use water spray or all purpose dry chemical to fight fires

Special Fire Fighting Procedures-- Fire fighters should wear self-contained breathing apparatus and full protective clothing if vials are involved in fire and contents are released or burning.

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Fire/Explosion Hazards----- Dangerous when heated to decomposition; emits highly toxic fumes containing chlorides and NO<sub>2</sub>.

Hazardous Decomposition Products Resulting From A Fire- Chlorides and NO<sub>2</sub>

## 6. Accidental Release Measures

Personal Precautions----- Immediately contact emergency response personnel. Keep unnecessary persons away.

Environmental Precautions---- Avoid contact of spilled materials and runoff with soil and surface waterways. Dispose of or treat all spill residues including contaminated soils following all federal, state and local regulations.

Methods for Cleaning Up----- Use suitable protective equipment (Section 8). Follow all fire prevention procedures (Section 5).

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, CHEMTREC provides a toll-free Hotline for chemical emergencies regarding spills, leaks, exposure or accidents:  
1-800-424-9300.

## 7. Handling and Storage

Special Precautions to be taken when:

Handling----- None for handling 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 laminar flow biological safety cabinet and that personnel preparing drugs

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of this class should wear surgical gloves and a closed front surgical-type gown with knit cuffs.

Storing----- Store in a cool, dry place. Dry crystalline material is stable at temperatures up to 40°C. Keep containers closed and well sealed.

Other----- 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.

### 8. Exposure Controls/Personal Protection

#### Exposure Guidelines

| <u>Component</u>    | <u>OSHA<br/>Permissible<br/>Exposure Limit<br/>(PEL)</u> | <u>ACGIH<br/>Threshold<br/>Limit Value<br/>(TLV)</u> | <u>Merck<br/>Exposure<br/>Control Limit<br/>(ECL)</u> |
|---------------------|--|--|---|
| Mechlorethamine HCL | Not established  | Not established                                      | Not established                                       |

#### Engineering Controls

Ventilation----- Ventilation is not necessary if material is contained in a vial. Vials should be reconstituted in a Class II Laminar Flow biological safety cabinet.

#### Personal Protective Equipment

Eye/Face----- Safety glasses should be worn when reconstituting compound.

Hands/Arms----- None required when handling sealed vials. The use of latex or PVC gloves is recommended when handling compound.

Respiratory----- No respiratory protection required when handling sealed vials or reconstituting in a biological safety cabinet. In manufacturing use a HEPA filter powered air purifying respirator or respirator of equivalent or greater protection if the potential exists for exposure to airborne dust.

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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 dust.

**9. Physical and Chemical Properties**

Appearance----- White or light yellow/brown crystalline  
hygroscopic powder, typically 10 mg of  
lyophilized powder in a small bottle to  
be reconstituted with injectable water.

Odor/Threshold Level (ppm)--- Not available

Boiling Point (°C/°F)----- Not applicable

Freezing Point (°C/°F)----- Not applicable

Melting Point----- 108 - 111°C

pH ----- Not applicable

Solubility in water----- Very soluble

Specific Gravity (Water = 1)- Not applicable

Vapor Density (Air=1)----- Not applicable

Vapor Pressure (mm Hg @ °C/°F)-- Not applicable

Volatile Components (% w/w)-- None

**10. Stability and Reactivity**

Stability (Normal Storage Conditions)-- Unstable, hygroscopic.

Storage Conditions to Avoid-- None

Thermal Stability/Instability Information-- Not available

Incompatibilities (Chemical Entities)-- Strong acids and bases.

Incompatibilities (Materials of Construction)-- Neutral or alkaline  
aqueous solution.

Hazardous Polymerizations---- None

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## 11. Toxicological Information

Primary Route(s) of Entry-----Inhalation: Yes  
Ingestion: No  
Skin Contact: No

### Toxicity Data

Quantitative Toxicity Data for formulation:

The intravenous LD50 of Mustargen is 2 mg/kg and 1.6 mg/kg in the mouse and rat, respectively.

For Mechlorethamine HCl

| <u>Test</u> | <u>Species</u> | <u>Route</u> | <u>Result</u> |
|-------------|----------------|--------------|---------------|
| LD50        | Rat            | Oral         | 10 mg/kg      |
| LD50        | Mouse          | Oral         | 20 mg/kg      |
| LD50        | Guinea Pig     | Oral         | 12 mg/Kg      |
| LD50        | Rat            | Subcutaneous | 19 mg/kg      |
| LD50        | Mouse          | Subcutaneous | 26 mg/kg      |
| LD50        | Mouse          | Intravenous  | 2 mg/kg       |
| LD50        | Dog            | Intravenous  | 1 mg/kg       |
| LD50        | Monkey         | Intravenous  | 0.34 mg/kg    |

Medical Conditions Aggravated by Exposure- Pre-existing bone marrow, GI, liver or neurological dysfunction, infertility and pregnancy.

### Effects of Acute Exposure

Eye Contact----- Compound has been shown to be corrosive.

Skin Contact----- Compound is a corrosive and a powerful vesicant.

Inhalation----- Compound is highly irritating to the mucous membranes of the respiratory tract.

Ingestion----- Data on oral toxicity in humans are not available. Animal data indicate mechlorethamine hydrochloride is highly toxic by the oral route. Since mechlorethamine hydrochloride is corrosive, it is potentially irritating to the upper GI tract.

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Effects of Chronic Exposure--- The compound is an alkylating agent that is cytotoxic to proliferating cells. It has been shown to cause mutations in a variety of genotoxicity tests and was embryotoxic and teratogenic in mice and rats. 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 and vomiting, and infertility.

Carcinogen Designation----- Mechlorethamine HCl is listed as a carcinogen by IARC and NTP.

## 12. Ecological Information

Environmental Fate----- Not available

Environmental Effects----- Not available

## 13. Disposal Considerations

Waste Disposal Information--- Avoid contact of spilled materials 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.

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**14. Transport Information**

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

ICAO/IATA----- Consumer Commodity, 9, ID8000  
Product Name: Mustargen

IMO----- Medicine, Solid, Toxic, N.O.S.  
(Mechlorethamine Hydrochloride mixture),  
6.1, UN3249, III, Limited Quantity.

Please note UN specification packaging,  
hazard labels are not required. Package  
must be marked "Dangerous goods in  
limited quantities of class 6.1."

Hazardous Substance-Reportable Quantity (RQ)--- Not applicable

**15. Regulatory Information**

U.S. Federal Regulations----- Not available

International Regulations---- Not available

State Regulations----- Not available

**16. Other Information**

Date Prepared----- September 1990

Last Revision Date----- August 2000  
(Revision: Section 7 Handling)

MSDS Coordinator----- 1-908-423-7926  
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U.S.A.

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to be accurate as of the date hereof, MERCK & CO., INC. makes no  
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