

**SAFETY DATA SHEET**

---

**SECTION 1: IDENTIFICATION**

---

**PRODUCT NAME:** Belrapzo™ (Bendamustine Hydrochloride) for Injection, 25 mg/mL

**MANUFACTURER:** Eagle Pharmaceuticals, Inc.

**ADDRESS:** 50 Tice Boulevard Suite 315  
Woodcliff Lake, NJ 07677

**PHONE:** (201) 326-5300

**EMERGENCY PHONE:** US & CANADA (800) 424-9300

OTHER +1 703-527-3887 (collect calls accepted)

**CHEMICAL FORMULA:** C<sub>16</sub>H<sub>21</sub>Cl<sub>2</sub>N<sub>3</sub>O<sub>2</sub>.ClH in non-aqueous solution

**PRODUCT USE:** Cytotoxic Agent

---

**SECTION 2: HAZARDS IDENTIFICATION**

---

**GHS Classification:**

Carcinogenicity (Category 2)

Reproductive toxicity (Category 1B)

This self-classification of the mixture is based on the presence of bendamustine hydrochloride at a concentration greater than the cut-off concentration of 0.1%, and of monothioglycerol.

**Signal word:** Warning

**Hazard Statements:**

May damage fertility or the unborn child  
Suspected of causing cancer

**Hazard Symbols:****Precautionary Statements:**

Do not handle until all safety precautions have been read and understood  
If exposed or concerned: Get medical attention/advice

---

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

---

**Bendamustine Hydrochloride**

CAS NO.	% WT
3543-75-7	~2.5%

**Monothioglycerol**

CAS NO.	% WT
96-27-5	~0.5%

NOTE: ~97% other nonhazardous ingredients

---

**SECTION 4: FIRST AID MEASURES**

---

# SAFETY DATA SHEET

**NAME OF PRODUCT:** Bendamustine Hydrochloride Injection, 25 mg/mL

**EYES:** Flush eyes with large amounts of water for at least 15 minutes. Seek medical attention if irritation persists.

**SKIN:** Wash skin thoroughly with large amounts of water. Seek medical attention if irritation persists.

**INGESTION:** Unlikely under normal conditions of handling. Contact physician or poison control center.

**INHALATION:** Unlikely under normal conditions of handling. Remove to fresh air. Contact physician if irritation persists.

**ACCIDENTAL INJECTION:** Flush injection site with water. Seek medical attention.

---

## SECTION 5: FIRE-FIGHTING MEASURES

---

**EXTINGUISHING MEDIA:** Any agent suitable for surrounding materials

**SPECIAL FIRE FIGHTING PROCEDURES:** None

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** None

**HAZARDOUS DECOMPOSITION PRODUCTS:** None

---

## SECTION 6: ACCIDENTAL RELEASE MEASURES

---

**ACCIDENTAL RELEASE MEASURES:** .

Small spills may be absorbed with a wet rag or similar absorbent material. Place in a suitable, properly labeled container for disposal.

Always wear gloves. Eye protection or additional body protection may be required for larger spills where splashing can occur.

---

## SECTION 7: HANDLING AND STORAGE

---

**HANDLING AND STORAGE:** Store refrigerated (2°C - 8°C). Use routine caution to avoid splashing.

**OTHER PRECAUTIONS:** Use routine caution in handling potent drugs

---

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

---

**ENGINEERING CONTROLS:** None needed under ordinary conditions of usage

**VENTILATION:** No special requirements

**RESPIRATORY PROTECTION:** None needed

**EYE PROTECTION:** Safety glasses recommended where where large quantities are handled and splashing may occur.

**SKIN PROTECTION:** Nitrile gloves. Long sleeves are recommended to protect skin.

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** N/A

# SAFETY DATA SHEET

**NAME OF PRODUCT:** Bendamustine Hydrochloride Injection, 25 mg/mL

**EXPOSURE GUIDELINES:** N/A

---

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

---

**APPEARANCE:** Clear, colorless to light yellow liquid

**ODOR:** None

**PHYSICAL STATE:** Liquid (viscous)

**pH:** 5-7

**BOILING POINT:** N/A

**MELTING POINT:** ~4°C

**VAPOR PRESSURE (mmHg):** N/A

**VAPOR DENSITY (AIR = 1):** N/A

**SPECIFIC GRAVITY (H<sub>2</sub>O = 1):** ~1.1

**EVAPORATION RATE:** Slow

**SOLUBILITY IN WATER:** Total

**PERCENT SOLIDS BY WEIGHT:** ~2

**PERCENT VOLATILE:** N/A

**VOLATILE ORGANIC COMPOUNDS (VOC):** N/A

---

## SECTION 10: STABILITY AND REACTIVITY

---

**STABILITY:** STABLE UNSTABLE  
X

**CONDITIONS TO AVOID:** None known

**INCOMPATIBILITY (MATERIAL TO AVOID):** Strong oxidizers, acids or alkalis

**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** None

**HAZARDOUS POLYMERIZATION:** Will not occur

# SAFETY DATA SHEET

**NAME OF PRODUCT:** Bendamustine Hydrochloride Injection, 25 mg/mL

---

## SECTION 11: TOXICOLOGICAL INFORMATION

---

### TOXICOLOGICAL INFORMATION:

No exposure via inhalation or ingestion is expected under normal conditions of use of this product.

Contact with eyes may cause irritation. Prolonged contact with skin may cause irritation.

The oral LD50 (rat) of pure Bendamustine Hydrochloride is 200 mg/kg

The oral LD50 (rat) of pure Monothioglycerol is 670 mg/kg

---

## SECTION 12: ECOLOGICAL INFORMATION

---

No data available

---

## SECTION 13: DISPOSAL CONSIDERATIONS

---

**WASTE DISPOSAL METHOD:** Waste material should be disposed of as appropriate for potent drugs, in accordance with federal, state and local regulations.

---

## SECTION 14: TRANSPORT INFORMATION

---

**U.S. DEPARTMENT OF TRANSPORTATION:** Not Regulated

**IATA:** Not Regulated

---

## SECTION 15: REGULATORY INFORMATION

---

### U.S. FEDERAL REGULATIONS

**TSCA (TOXIC SUBSTANCE CONTROL ACT):** Exempt

**CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT):** N/A

**SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):**

**311/312 HAZARD CATEGORIES:** N/A

**313 REPORTABLE INGREDIENTS:** N/A

**STATE REGULATIONS:** N/A

# SAFETY DATA SHEET

**NAME OF PRODUCT:** Bendamustine Hydrochloride Injection, 25 mg/mL

## SECTION 16: OTHER INFORMATION

---

**SHEET DATE:** April 8, 2019

**CONTACT PERSON FOR ADDITIONAL INFORMATION:** Amy MacMichael, Director, Procurement

**DISCLAIMER:** The information in this sheet is believed to be accurate and represents the best information currently available. However, we make no warranty express or implied, with respect to such information, and we assume no liability resulting from its use.