

# Bendamustine Hydrochloride for Injection, USP

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : Bendamustine Hydrochloride for Injection, USP  
Other means of identification : 25 mg lyophilized powder in a 26 mL amber single-dose vial, NDC 55150-391-01  
100 mg lyophilized powder in a 60 mL amber single-dose vial, NDC 55150-392-01

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

Eugia US LLC  
279 Princeton Hightstown Road  
East Windsor, NJ 08520

#### 1.4. Emergency telephone number

Emergency number : 1-888-238-7880

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS US classification

Acute Tox. 3 (Oral) H301  
Muta. 2 H341  
Carc. 2 H351  
Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

#### 2.2. Label elements

##### GHS US labeling

Hazard pictograms (GHS US) :



GHS06

GHS08

Signal word (GHS US) :

Danger

Hazard statements (GHS US) :

H301 - Toxic if swallowed  
H341 - Suspected of causing genetic defects  
H351 - Suspected of causing cancer  
H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS US) :

P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P301+P310 - If swallowed: Immediately call a poison center or doctor.  
P308+P313 - If exposed or concerned: Get medical advice/attention.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P330 - Rinse mouth.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

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### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	GHS US classification
D-Mannitol	(CAS-No.) 69-65-8	2.125	Not classified
Bendamustine Hydrochloride Monohydrate	(CAS-No.) 1374784-02-7	1.25	Acute Tox. 3 (Oral), H301 Muta. 2, H341 Carc. 2, H351 Repr. 2, H361

Full text of hazard classes and H-statements : see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

- First-aid measures after inhalation : If not breathing, give artificial respiration.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.
- First-aid measures after ingestion : Go into open air and ventilate suspected area.

#### 4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after inhalation : Prolonged inhalation of dust may cause respiratory irritation.
- Symptoms/effects after skin contact : May cause skin irritation.
- Symptoms/effects after eye contact : May cause eye irritation.
- Symptoms/effects after ingestion : Toxic if swallowed.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

#### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

#### 5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : No special measures required.

##### 6.1.1. For non-emergency personnel

No additional information available

##### 6.1.2. For emergency responders

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

- For containment : Stop the flow of material, if this is without risk.
- Methods for cleaning up : Recycle product or dispose safely.

#### 6.4. Reference to other sections

No additional information available

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Do not eat, drink or smoke when using this product.

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### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : The product may be stored up to 25°C (77°F) with excursions permitted up to 30°C (86°F).

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### D-Mannitol (69-65-8)

Not applicable

#### Bendamustine Hydrochloride Monohydrate (1374784-02-7)

Not applicable

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.  
Hand protection : Use neoprene or rubber gloves.  
Eye protection : In case of dust production: protective goggles.  
Skin and body protection : Wear suitable working clothes.  
Respiratory protection : Wear NIOSH approved respirator when handling.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Lyophilized powder  
Color : White to off-white  
Odor : Odorless  
Odor threshold : No data available  
pH : No data available  
Melting point : No data available  
Freezing point : No data available  
Boiling point : No data available  
Flash point : No data available  
Relative evaporation rate (butyl acetate=1) : No data available  
Flammability : No data available  
Vapor pressure : No data available  
Relative vapor density at 20°C : No data available  
Relative density : No data available  
Solubility : No data available  
Partition coefficient n-octanol/water (Log Pow) : No data available  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity, kinematic : No data available  
Viscosity, dynamic : No data available  
Explosion limits : No data available  
Explosive properties : No data available  
Oxidizing properties : No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

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### 10.3. Possibility of hazardous reactions

Will not occur.

### 10.4. Conditions to avoid

Air contact.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

#### Bendamustine Hydrochloride for Injection, USP

ATE US (oral)	100 mg/kg body weight
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#### D-Mannitol (69-65-8)

LD50 oral rat	13500 mg/kg
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ATE US (oral)	13500 mg/kg
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#### Bendamustine Hydrochloride Monohydrate (1374784-02-7)

ATE US (oral)	100 mg/kg body weight
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Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Suspected of causing genetic defects.

Carcinogenicity : Suspected of causing cancer.

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

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## Safety Data Sheet

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not applicable

#### International Air Transport Association (IATA)

In accordance with IATA

Not applicable

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

##### D-Mannitol (69-65-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### 15.2. US State regulations

No additional information available

### SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Carc. 2	Carcinogenicity Category 2
Muta. 2	Germ cell mutagenicity Category 2
Repr. 2	Reproductive toxicity Category 2
H301	Toxic if swallowed
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*