

Bortezomib for Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Bortezomib for Injection
Other means of identification : 3.5 mg per single dose vial, NDC 55150-337-01

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

AuroMedics
279 Princeton Highstown 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

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) :



GHS08

Signal word (GHS US) : Warning
Hazard statements (GHS US) : 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.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
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

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	91	Not classified
Bortezomib	(CAS-No.) 390800-88-1	9	Acute Tox. 1 (Oral), H300 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 2, H361 STOT RE 1, H372

Bortezomib for Injection

Safety Data Sheet

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	: 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	: May be harmful 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

No additional information available

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	: Place in a suitable container and dispose according to local, state and federal regulations.

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.
-------------------------------	---

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store vials at 20°C to 25°C (68°F to 77°F)
--------------------	--

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

D-Mannitol (69-65-8)

Not applicable

Bortezomib for Injection

Safety Data Sheet

Bortezomib (390800-88-1)

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 cake or 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 (solid, gas)	: 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.

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.

Bortezomib for Injection

Safety Data Sheet

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Bortezomib for Injection	
ATE US (oral)	100 mg/kg body weight
D-Mannitol (69-65-8)	
LD50 oral rat	13500 mg/kg
ATE US (oral)	13500 mg/kg
Bortezomib (390800-88-1)	
ATE US (oral)	0.5 mg/kg body weight

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Causes serious eye damage.
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

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.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Bortezomib for Injection

Safety Data Sheet

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. 1 (Oral)	Acute toxicity (oral) Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
H300	Fatal if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure

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.