

SAFETY DATA SHEET

Product Name	Bortezomib for Injection 3.5 mg/Vial	Page No 1 of 4
---------------------	---	-----------------------

1. Identification of the substance/mixture and the company/undertaking

Product Name: Bortezomib for Injection 3.5 mg/Vial

Chemical Family: Mixture

Intended use: pharmaceutical product used as Antineoplastic drug

Details of the manufacturer:

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. Hazards Identification

Exposure: Inhalation, Ingestion, Skin contact, Eye contact

Target Organs: Eye, skin, mucous membranes, gastrointestinal system

Acute Effects: May cause eye irritation., May cause skin irritation., May cause gastrointestinal effects.,

Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

Chronic Effects: May cause skin irritation.

Carcinogenicity: formulation not listed by NTP, IARC or OSHA

GHS Classification Health Hazards:

Germ cell mutagenicity (Category 2) H341 Suspected of causing genetic defects.

Carcinogenicity (Category 1B)H350 May cause cancer.

D Reproductive toxicity (Category 1B)H360D May damage the unborn child.

F Reproductive toxicity (Category 1B) H360F May damage fertility.

Signalword: Danger



Label:

Precautionary statements:

- P201 Obtain special instructions before use.

- P260 Do not breathe dust

- P281 Use personal protective equipment as required.

- P308 + P313 IF exposed or concerned: Get medical advice/attention.

Additional Health Information - Some components of this product are considered potential reproductive effectors at high dosage. Refer to Section 11 (Toxicological information) for additional information on this product.

SAFETY DATA SHEET

Product Name	Bortezomib for Injection 3.5 mg/Vial	Page No 2 of 4
---------------------	---	-----------------------

- The most common dose-dependent adverse effects associated with therapeutic treatments include diarrhea, nausea, vomiting, sores in mouth and throat, abdominal pain, constipation, loss of appetite, dehydration, rash and dry, itchy or discolored skin.

- Additional effects may include nail problems, hair loss, tiredness, weakness, dizziness, headache, fever, chest, back, joint and muscle pain, trouble sleeping, taste problems and palms of the hands or soles of the feet tingle, become painful or swollen.

Note: Cytostatic in general have to be classified as potentially carcinogenic, teratogenic and mutagenic. During handling any occupational exposure as well as environmental contamination have to be avoided.

3. Composition/Information on Ingredients

C.A.S. No	: 179324-69-7
Molecular Formula	: C ₁₉ H ₂₅ BN ₄ O ₄
Formula Weight	: 384.24
Chemical Name	: [(1R)-3-methyl-1-[(2S)-1-oxo-3-phenyl-2-[(pyrazinylcarbonyl) amino]propyl] amino]butyl] boronic acid

4. First Aid Measures

Eye contact

- Rinse immediately with tap water for 10 minutes - open eyelids forcibly
- consult a physician if irritation persists

Skin contact

- Remove immediately contaminated clothes, wash affected skin with water and soap
- do not use any solvents
- consult a physician if skin irritation persists

Inhalation

- Remove the casualty to fresh air and keep him/her calm
- get medical treatment

Ingestion

- Summon a physician immediately
- let drink repeatedly plenty of water and induce vomiting (only if conscious), repeat several times

Note to physician

- treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing media	- Water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	- Not applicable
Specific hazards	- Very high probability of ignition of dust whirled up - Formation of toxic and corrosive combustion gases (hydrogen fluoride, nitrogen oxides) possible - Consider danger for the environment: dike spilled liquid
Protection of fire-fighters	- Precipitate gases/vapours/mists with water spray - Use self-contained breathing apparatus - Avoid skin contact

6. Accidental Release Measures

Personal precautions - ensure adequate ventilation

- keep people away and stay on the upwind side

Environmental protection - do not allow to enter drains or waterways

- if the substance reaches waters or the sewer system, inform the competent authority
- the solvent should be held back due to environmental protection

SAFETY DATA SHEET

Product Name	Bortezomib for Injection 3.5 mg/Vial	Page No 3 of 4
---------------------	---	-----------------------

Methods for cleaning up - collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

7. Handling and Storage

General Handling: Minimize dust generation and accumulation. Avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions: Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

8. Exposure Controls/Personal Protection

Exposure Limits

Data not available

Specific Engineering Controls (*such as ventilation, enclosed process*)

Not applicable

Personal Protective Equipment

Safety glasses with side shields.

Safety gloves

Protective clothing

Chemical resistant footwear

9. Physical and Chemical Properties

Appearance: White to off-white lyophilized powder

10. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

11. Toxicological Information

Acute oral toxicity: No data available

Acute inhalation toxicity: No data available.

Acute dermal toxicity: No data available.

Skin irritation: Non-irritant (rabbit)

Eye irritation: No data available.

Reproductive toxicity: No data available.

Teratogenicity: No data available.

Aspiration hazard: No data available.

Carcinogenicity : NTP?No IARC Monographs ?No OSHA Regulated? No

SAFETY DATA SHEET**Product Name****Bortezomib for Injection 3.5 mg/Vial****Page No 4 of 4****12. Ecological Information****[Aquatic Toxicity]**

No information is available about the potential of this product to produce adverse environmental effects.

13. Disposal Considerations**Waste from residues**

- Observe local/national regulations regarding waste disposal
- Incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

14. Transport Information

Note : Not classified by transport regulations, proper shipping name non-regulated

15. Regulatory Information

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

Emergency Response Guide Book: N/A

Special precautions for users: N/D

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.