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Section 1 - Identification

- (a) **Product Identifier:** Bortezomib for Injection
- (b) **Product Code:** 83634-208-10
- Common/Trade Name:** Velcade; Bortezomib
- Chemical Name:** [(1R)-3-methyl-1-[[[(2S)-1-oxo-3-phenyl-2-[(pyrazinylcarbonyl)amino]propyl]amino] butyl] boronic acid
- Chemical Family:** Proteasome Inhibitor
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229


Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Reproductive toxicity. Category 1A
Specific Target Organ Toxicity – STOT
Repeated exposure RE. Category 2 (Nervous System)
Reproductive toxicity. Effects on or via lactation.

(b) Signal Word, Hazard statement(s), Symbol(s), and/ or Precautionary	(c) Description of Hazards:
GHS Signal Word:	Danger
GHS Hazard Statement:	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.
GHS Symbols:	

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<p>GHS Precautionary Statements:</p>	<p>P203 – Obtain, read and follow all safety instructions before use. P260 – Do not breathe dust/fume/gas/mist/vapors/spray. P264 – Wash hands and skin 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+P316 – IF SWALLOWED: Get emergency medical help immediately. P302+P352 – IF ON SKIN: wash with plenty of soap and water. P318 – If exposed or concerned, get medical advice. P319 – Get medical help if you feel unwell. P321 – Specific treatment (see information on the product label and safety data sheet). P332+P317 – If skin irritation occurs: Get medical help. P330 – Rinse mouth. P362+P364 – Take off contaminated clothing and wash it before reuse. P405 – Store locked up. P501 – Dispose of contents/container according to local, state, or federal waste disposal regulations.</p>
<p>Other Hazards</p>	<p><i>Potential Health Effects:</i> This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients. May cause irritaiton to eyes, skin and respiratory tract, nausea, vomiting, rash, diarrhea.</p> <p><i>Acute Health Effects:</i> The effects reported are from use of the drug product clinically or the testing of the drug substance in laboratory animals. In patients given the drug, Bortezomib produces many of the acute offsets typical of drugs that kill rapidly growing cells, including effects on the hematological system, fatigue, nausea, vomiting, diarrhea, and fever. Other organ systems reported to be effected include the respiratory tract (shortness of breath), and nervous system (headache, dizziness, and peripheral neuropathy). Some of the acute effects may be delayed in onset, such as the effects on the hematological system, which are characterized by decreased white blood cells, platelets and red blood cells, and may occur several days or weeks following the acute exposure. These effects may potentially occur from acute (severe spill) or repeated overexposure in occupational settings.</p> <p><i>Chronic Health Effects:</i> Based on other antineoplastic agents and data on Bortezomib, the spectrum of effects after chronic exposure would be expected to be similar to those after acute exposure. Initial repeated dose studies in laboratory animals have shown similar effects as acute studies.</p> <p><i>Target Organs:</i> Eyes, Skin, Respiratory system, Hematological system, peripheral nervous system, liver, kidney, reproductive system.</p>

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Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
[(1R)-3-methyl-1-[[[(2S)-1-oxo-3-phenyl-2-[(pyrazinylcarbonyl)amino]propyl]amino] butyl] boronic acid	Bortezomib	9%	179324-69-7	N/A
(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol	Mannitol	91%	87-78-5	NA

Section 4 – First Aid Measures

- Eye Exposure:** Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
- Skin Exposure:** Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
- Ingestion:** If swallowed, do NOT induce vomiting. Call physician or poison control center immediately. Never give anything by mouth to an unconscious person.
- Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
- General:** Material is a cytotoxic anticancer drug.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media:** Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.
- (b) **Hazardous Combustion Products:** Carbon monoxide and nitrogen oxides.
- (c) **Special Protective Equipment / Precautions:** As in any fire, wear self-contained breathing apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear. Evaluate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined space without full protective gear. If possible, contain fire run-off water.

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Section 6 - Accidental Release Measures

Health and Safety Precautions: Dispose of all collected material as pharmaceutical biological/medical waste in accordance with applicable local, state, and federal waste disposal regulations.

Measures for Environmental Protections: Liquid form; absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. Provide ventilation. Clean up spills immediately observing precautions in the protective equipment section. After removal, flush spill area with soap and water to remove trace residue.
Solid or Powder form; do not raise the dust. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize powder from entering the air. Add excess liquid to allow for the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill material into a leak-proof container suitable for disposal. After removal, flush spill area with soap and water to remove trace residue.

Section 7 - Handling and Storage

General Handling: Use with adequate ventilation. Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor, or mist. Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personnel protective equipment if needed). Wash thoroughly after handling.

Storage Conditions: Unopened vials may be stored at controlled room temperature 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). Protect from light, retain in carton until time of use. Store in a cool, dry, well-ventilated area away from sources of heat and incompatible materials. Keep container tightly closed when not in use. Protect against physical damage.


Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

None currently established by OSHA, NIOSH or ACGIH. Millennium considers the active pharmaceutical ingredient to be highly toxic and potent because of its significant potency and cytotoxicity.

(b) Engineering Controls

Use appropriate engineering controls such as process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Good general ventilation should be sufficient to control airborne levels. Where such systems are not effective, wear suitable personal protective equipment, which performs satisfactorily and meets OSHA or other recognized standards. Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.


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(c) Individual Protection Measures

Eye Protection:	Wear appropriate protective glasses or splash goggles as described by 29 CFR 1910.133, OSHA eye and face protection regulation, or the European standard EN 166.
Skin Protection:	Wear appropriate protective gloves and other protective apparel to prevent skin contact. Consult manufacturer's data for permeability data.
Respiratory Protection:	A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits. Protection provided by air purifying respirators is limited. Use a positive pressure air supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection.
Additional Information:	Facilities storing or utilizing this material should be equipped with an eyewash and a deluge shower safety station. Decontaminate all protective equipment after use. Exercise extreme care when working with sharps/needles/syringes and potent drugs.

Section 9 - Physical and Chemical Properties

(a)	Appearance	White to off-white cake or powder
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	Not available
(e)	Melting Point:	140 – 150°C
(f)	Initial Boiling Point:	Not available
(g)	Boiling Point:	Not available
(h)	Flash Point (Liquid) (°C)	Not available
(i)	Evaporation Rate:	Not available
(j)	Flammability	Not available
(k)	Upper Lower Flammability or Explosion Limits	Not available
(l)	Vapor Pressure (kPa):	Not available
(m)	Vapor Density:	Not available
(n)	Relative Density	Not available
(o)	Solubility(ies)	Soluble in water (3.3 to 3.8 mg/mL at pH range of 2 to 6.5)
(p)	Partition Coefficient: n-octanol/water	Not available

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(q)	Auto-ignition Temperature	Not available
(r)	Decomposition Temperature	Not available
(s)	Viscosity	Not available


Section 10 - Stability and Reactivity

(a)	Reactivity	Stable under normal conditions of use.
(b)	Chemical Stability	Stable at normal temperatures and pressures
(c)	Possibility of Hazardous Reactions	Hazardous polymerization does not occur
(d)	Conditions to Avoid	Protect from light
(e)	Incompatible Materials	Avoid contact with oxidizing agents
(f)	Hazardous Decomposition Products	Carbon oxides. Nitrogen oxides (NO _x)

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, inhalation, skin contact, mucous membranes.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	<p><i>Eye:</i> Moderate to severe eye irritant</p> <p><i>Skin:</i> Moderate to severe skin irritant</p> <p><i>Inhalation:</i> Inhalation data not identified. Based on the high acute toxicity reported in non-clinical IV studies, a potential for toxicity via the inhaled route cannot be excluded.</p> <p><i>Ingestion:</i> Very toxic by ingestion.</p>

<p>(c)</p>	<p>Delayed and immediate effects and chronic effects from short and long term exposure</p>	<p>Repeated occupational overexposure may cause fatigue and fever, and effects on the hematological (decreases in hemoglobin/anemia, blood counts and platelets), gastrointestinal (nausea, diarrhea, vomiting, abdominal pain), and nervous systems (headache, peripheral neuropathy). May affect fertility and fetal development based on mechanism and animal toxicity studies.</p> <p><i>Mutagenicity:</i> Bortezomib API showed clastogenic activity in the in vitro chromosomal aberration assay using Chinese hamster ovary cells, but bortezomib was not genotoxic in the in vitro mutagenicity assay (Ames test), or in the in vivo micronucleus assay in mice.</p> <p><i>Reproductive Toxicity:</i> Fertility studies have not been performed, but degenerative effects have been observed in the ovaries and testes of rats in a 6 month toxicity study. Bortezomib API could affect male or female fertility.</p> <p><i>Teratogenicity:</i> Not conducted</p>
<p>(d)</p>	<p>Other Toxicological Information</p>	<p>Bortezomib API is a cytotoxic antineoplastic compound that exerts its biological effects by inhibiting the activity of the proteasome, a macromolecular complex found in all cells that plays a critical role in protein homeostasis. In local tolerance studies bortezomib showed minimal tissue irritancy; however direct skin contact should be avoided. Bortezomib API is acutely lethal in animals, when delivered intravenously at sufficient doses, and death is due to cardiovascular effects. Systemic, therapeutic exposure to bortezomib in humans is associated with a variety of adverse events, including peripheral neuropathy, hypotension, cardiac disorders, pulmonary disorders, reversible posterior leukoencephalopathy syndrome (RPLS), gastrointestinal disturbances (nausea, diarrhea, constipation, vomiting), decreased platelet count and neutrophil counts in the blood, tumor lysis syndrome, and liver disturbances.</p>

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(d) Acute Toxicity:

Not available.

Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

(a)	Ecotoxicity	No Data Available
(b)	Persistence and degradability	No Data Available
(c)	Bioaccumulative potential	No Data Available
(d)	Mobility in soil	No Data Available
(e)	Other Adverse Effects	No Data Available

Section 13 - Disposal Considerations

Waste Disposal: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.


Section 14 - Transport Information

DOT

DOT Shipping Name:	Not Regulated.
DOT UN Number	Not Regulated.
DOT Hazard Class	Not Regulated.
DOT Packing Group	Not Regulated.

IATA

IATA Shipping Name:	Not Regulated.
IATA UN Number	Not Regulated.
IATA Hazard Class	Not Regulated.
IATA Packing Group	Not Regulated.

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not regulated
 CERCLA - Not on this list
 SARA 302 - Not on this list
 SARA 313 - Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy
 10 N. Martingale Road, Suite 225
 Schaumburg, IL 60173
 847-773-4901

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals

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HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System