Bortezomib for Injection

01. IDENTIFICATION OF THE SUBSTANCE/PREPARATION & THE COMPANY/UNDERTAKING

GETWELL PHARMACEUTICALS
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Material Name : Bortezomib for Injection
Synonyms: PS-341, MLN-341, MG-341, NSC-681239
Product Use/Restriction: The following MSDS applies to the formulated lyophilized product only. If handling bortezomib for Injection in manufacturing situations, consult the MSDS for the active ingredient and take appropriate precautions.

02 . HAZARDS IDENTIFICATION

Emergency Overview:
Contains a pharmaceutically active ingredient. Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients. Avoid skin contact, eye contact, and inhalation. Exercise due care: wear suitable protective clothing, gloves and eye/face protection.
Route of Exposure: Eyes. Skin. Inhalation. Ingestion.
Eye: Moderate to severe eye irritant
Skin: Moderate to severe skin eye irritant
Inhalation: Toxic by inhalation.
Ingestion: Very toxic by ingestion
Chronic Health Effects: 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.
Target Organs: No target organ toxicity has been identified to date.

03. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent
Bortezomib	179324-69-7	10% by weight
Excipients (mannitol)	69-65-8	90% by weight

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04. FIRST AID MEASURES

Eye Contact: 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 Contact: 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.
Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion: If swallowed, do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.
Note to Physicians: Material is a cytotoxic anticancer drug

05. FIRE FIGHTING MEASURES

Flammable Properties: Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
Flash Point: Not determined.
Auto Ignition Temperature: Not determined.
Lower Flammable/Explosive Limit: Not determined.
Upper Flammable/Explosive Limit: Not determined.
Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media: Use alcohol foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.
Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts: Carbon monoxide and nitrogen oxides.

06. ACCIDENTAL RELEASE MEASURES

Environmental Precautions: Dispose of all collected material as pharmaceutical biological/medical waste in accordance with applicable local, state and federal waste disposal regulations
Spill Cleanup Measures: 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 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 materials into a leak-proof container suitable for disposal.After removal, flush spill area with soap and water to remove trace residue.

07. HANDLING AND STORAGE

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).
Storage: Store at 25ºC +/- 5ºC away from sunlight. 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. Shelf life 36 months.
Hygiene Practices: Wash thoroughly after handling.

08. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Use appropriate engineering control 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.
Eye/Face 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 Description: 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.
Other Protective: 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.
Guideline Info: 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.

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09. PHYSICAL AND CHEMICAL PROPERTIES

Physical State Appearance: White powder.
Boiling Point: Not determined.
Melting Point: 140 – 150 °C
Density: Not determined.
Solubility: approximately 3.0 mg/mL in aqueous solution
Vapor Density: Not determined.
Percent Volatile: Not determined.
Evaporation Rate: Not determined.
pH: Not determined.
Molecular Formula: C19H25BN4O4
Molecular Weight: Mixture
Flash Point: Not determined.
Auto Ignition Temperature: Not determined.
Vapor Pressure: Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Pharmacologically stable
Hazardous Polymerization: Not reported.
Conditions to Avoid: Not known
Incompatible Materials: Not known

11. TOXICOLOGICAL INFORMATION

Inhalation: Not tested.
Ingestion: Not tested.
Carcinogenicity: IARC, NTP, and OSHA studies not conducted
Mutagenicity: Bortezomib 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.
Reproductive Toxicity: 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 could affect male or female fertility.
Teratogenicity: Not conducted
Other Toxicological Information: Bortezomib 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 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.

12.0 ECOLOGICAL INFORMATION

Ecotoxicity: No Data
Effect of Material On Aquatic Life: No Data

13.0 DISPOSAL CONSIDERATIONS

Waste Disposal: All wastes containing the material should be properly labeled. Dispose of any waste residues according to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

14.0 TRANSPORT INFORMATION

IATA: This substance is considered to be non-hazardous for transport.
IMO: This substance is considered to be non-hazardous for transport.
RID/ADR: This substance is considered to be non-hazardous for transport.

15.0 REGULATORY INFORMATION

TSCA Inventory Status: Not listed
SARA: No Data
California PROP 65: No Data
Canada WHMIS: Drugs are exempt, however, if not a drug, the most appropriate classification for Bortezomib for Injection® would be Class D, Division 1, Subdivision A; based on its potential to
be cytotoxic and a reproductive or developmental toxicant
Risk Phrases: R 28 Very toxic if swallowed.
R 38 Irritating to skin.
R 41 Risk of serious damage to eyes.
R 48 Toxic: danger of serious damage to health by prolonged exposure.
R 62 Possible risk of impaired fertility.
R 63 Possible risk of harm to the unborn child.
Safety Phrase: S 24/25Avoid contact with skin and eyes.
S 26In case of contact with eyes, rinse immediately with plenty of water and
seek medical advice.

S 28 After contact with skin, wash immediately with plenty of water.
S 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

16.0 ADDITIONAL INFORMATION

HMIS Fire Hazard: 1
HMIS Health Hazard: 4
HMIS Reactivity: 0
HMIS Personal Protection: X
Other Information: Version 2.0
MSDS Preparation Date: 07/03/2017
MSDS Author: Getwell Pharmaceuticals
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