

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Bort-AUS/DP-002

Effective Date: 30th June 2026

BORTEZOMIB POWDER FOR INJECTION 1 MG/VIAL, AND 3.5 MG/VIAL

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Bortezomib Powder for Injection
1 mg/vial, and 3.5 mg/vial

Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street,
Melbourne, VIC, 3000, Australia

Telephone: 1800 222 673
(hours 8:30am – 4:30pm)

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Reproductive Toxicity	: Category 2
Serious Eye Damage/Eye Irritation	: Category 1
Acute Oral Toxicity	: Category 2
Skin corrosion/irritation	: Category 1C
Specific target organ toxicity, repeated exposure	: Category 1

Label Elements:



Signal Word: Danger

Hazard Statements:

H300	- Fatal if swallowed
H314	- Causes severe skin burns and eye damage
H361	- Suspected of damaging fertility or the unborn child
H372	- Causes damage to organs through prolonged or repeated exposure

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Precautionary Statements:

- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
- P264 - Wash hands 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 + P330 - If swallowed: Rinse mouth. Do not induce vomiting.
- + P331
- P303 + P361 - If on Skin or hair: remove take/off immediately all contaminated clothing. Rinse skin with water/shower.
- + P353
- P304 + P340 - If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P305 + P351 - If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- + P338
- P308 + P313 - If exposed or concerned: Get medical advice/attention.
- P363 - Wash contaminated clothing before reuse.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, state, federal and provincial regulations.

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Bortezomib.

Inactive: Mannitol.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Bortezomib	179324-69-7	-	Repr. 2 (H361) Acute Tox 2 (H300) Skin Corr. 1C (H314) STOT-R1 (H372)	*
Mannitol	69-65-8	200-711-8	Not Listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing and shoes and place in sealable, properly labeled waste disposal bag. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. If experiencing difficulty breathing, seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Medical Attention and Special Treatment: Provide general supportive measures and treat symptomatically. Chemical burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Keep victim warm. Keep victim under observation. Symptoms may be delayed.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. Extinguish fires with CO₂, extinguishing powder, foam, dry sand, water fog or mist.

Special Hazards Arising from the Substance or Mixture: Avoid generating dust. Fine dust dispensed in air in sufficient concentration and the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed.

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: May form combustible dust concentrations in air.

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SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Keep unnecessary personnel away. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up: Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Combustible dust clouds may be created where operations produce fine material (dust). Handling and processing operations should be conducted in accordance with 'best practices' (e.g. NFPA-654). Explosion-proof general and local exhaust ventilation. Do not breathe dust. When using, do not eat, drink or smoke. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. 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

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PPE. Releases to the environment should be avoided. 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.

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Bortezomib:

OEL TWA-8 Hr : 530 ng/m³

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposures. Explosion-proof general and local exhaust ventilation. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks. Eye wash facilities and emergency shower must be available when handling this product.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

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Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Powder
Colour	: White to off-white
Odour	: No data available
Odour Threshold	: No data available
Solvent Solubility	: No data available
Water Solubility	: ± 80 mg/mL
pH	: Not applicable
Melting Point (°C)	: 165°C
Boiling Point and boiling range (°C)	: Not applicable
Partition Coefficient (<i>n</i> -octanol/water)	: No data available
Decomposition Temperature (°C)	: No data available
Evaporation Rate (Gram/s)	: Not applicable
Vapour Pressure (kPa)	: Not applicable
Vapour Density (g/ml)	: Not applicable
Relative Density	: No data available
Viscosity	: No data available
Auto-ignition Temperature (Solid) (°C)	: No data available
Flammability (Solids)	: Capable of catching on fire
Flash Point (Liquid) (°C)	: Not applicable
Upper Flammability or Explosive Limits (Liquid) (% by Vol.)	: Not applicable
Lower Flammability or Explosive Limits (Liquid) (% by Vol.)	: Not applicable

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport. Bortezomib oxidizes when in solution.

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Keep away from heat, sparks and open flame. Minimise dust generation and accumulation.

Incompatible Materials and Possible Hazardous Reactions: As a precautionary measure, keep away from strong oxidizers.

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Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient, bortezomib.

Information on likely routes of exposure:

Inhalation: Dust may irritate respiratory system.

Skin contact: Cause severe skin burns.

Eye contact: Cause serious eye damage.

Ingestion: Fatal if swallowed. Causes digestive tract burns.

Symptoms related to the physical, chemical and toxicological characteristics:

Burning pain and severe corrosive skin damage. Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Dust may irritate the respiratory system. Prolonged exposure may cause chronic effects.

Information on toxicological effects:

Acute Toxicity: Fatal if swallowed.

Bortezomib:

Species	Route	End Point	Dose
Rat	Oral	LD 50	<5 mg/kg

LD50: Lethal Dose 50%

Skin corrosion/irritation: Causes severe skin burns.

Corrosivity: Result: Acute dermal irritation study (OECD 404 (equivalent), rabbit, 4 h exposure): severe irritant and corrosive.

Serious eye damage/eye irritation: Causes serious eye damage.

Respiratory or skin sensitization:

Respiratory sensitization: No data available.

Skin sensitization: No data available.

Reproduction Toxicity: Suspected of damaging fertility or the unborn child.

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Reproductivity: Result: Embryo-fetal-developmental effects were both observed in rats and rabbits (at doses of 0.075 mg/kg and 0.05 mg/kg, respectively), but not below maternally toxic doses.

Result: In a developmental toxicity study (OECD 414) in rats, the NOAEL for maternal and fetal effects was 0.050 mg/kg/day (0.3 mg/m²/day).

Result: In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity and embryo-fetal development was 0.025 mg/kg/day (0.28 mg/m²/day).

Germ cell mutagenicity: Not classified

Germ cell mutagenicity: Ames test

Result: Bortezomib showed no genotoxic activity in the Ames assay (OECD 471).

Germ cell mutagenicity: Chromosome Aberration

In vitro. In CHO (Chinese hamster ovary) cells (OECD 473).

Result: Clastogenic activity (chromosomal aberrations) was observed. The clastogenic activity is expected based on the compound's mechanism of action and its effect on the cell-cycle.

Germ cell mutagenicity: Micronucleus

Result: Negative results were obtained in the in vivo micronucleus assay in mice (OECD 474).

Carcinogenicity: No studies available.

Specific target organ toxicity – single exposure: Not classified.

Bortezomib: Single dose IV studies (OECD 417) were conducted in mice, rats, dogs and monkeys, with the monkey being identified the most rigorous assessment of acute toxicity. In the cynomolgus monkey, the maximum tolerated dose (MTD) was 1.2 mg/m² (0.1 mg/kg) and the minimum lethal dose (MLD) was 3.0 mg/m² (0.25 mg/kg). Mouse MTD IV is 1.0 mg/kg; rat MTD IV is 0.10 mg/kg and dog MTD IV is 0.18 mg/kg.

Specific target organ toxicity – repeated exposure: May cause damage to organs through prolonged or repeated exposure.

Bortezomib: The MTD in a 6-month repeat dose study in rats was 0.10 mg/kg (0.6 mg/m²). Target organs were the GI tract (at ≥ 0.10 mg/kg) and the hematopoietic and lymphoid systems (at ≥ 0.05 mg/kg). In a 9-month (13 cycles) IV repeat dose studies in cynomolgus monkeys, a NOAEL was not identified but the MTD was defined as 0.05 mg/kg, based on target organ toxicity observed in the bone marrow, lymphoid tissue (at ≥ 0.05 mg/kg) and the peripheral nervous system, kidney, and GI tract (at 0.075 mg/kg). Incomplete reversibility of the toxic effects was observed in both species.

Aspiration hazard: Not relevant due to the form of the product.

Chronic effects: May cause damage to organs through prolonged or repeated exposure.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity: Not expected to be harmful to aquatic organisms.

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Persistence and Degradability: No data is available on the degradation of any ingredients in the mixture.

Bio-accumulative Potential:
Partition Coefficient: 2.004

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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 wastewater.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

US DOT shipping description:

UN number: UN2928

UN proper shipping name: Bortezomib

Transport hazard classes and packing group: Class 6.1, Subsidiary risk 8; Packing Group II.

Environmental hazards: No.

ERG Code: 6C

Special precautions for users: Read safety instruction.

IMDG shipping description:

UN number: UN2928

UN proper shipping name: Bortezomib

Transport hazard classes and packing group: Class 6.1, Subsidiary risk 8; Packing Group II.

Environmental hazards: No.

EmS: F-A, S-B

Special precautions for users: Read safety instruction.

Transport in bulk according to Annex II or MARPOL 73/78 and the IBC Code: Not applicable.

SECTION 15 - REGULATORY INFORMATION

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Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This product may only be used for TSCA Exempt purposes such as R&D or Food, Drug or Cosmetic use.

All components are listed on or exempt from the U.S. EPA TSCA Inventory List.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed

SARA 304 Emergency release notification: Not regulated.

OSHA Specifically Regulated Substances (29 CF 1910.1001-1053): Not listed.

Toxic Substances Control Act (TSCA): All components are either listed on the TSCA 8(b) inventory and designated "active" or exempt from listing.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance: Not listed.

SARA 311/312 Hazardous chemical: No (exempt)

SARA 313 (TRI reporting): Not regulated.

Other federal regulations

Clear Air Act (CAA) Section 112 Hazardous Air Pollutant (HAPs) List: Not regulated.

Clear Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not regulated.

Safe Drinking Water Act (SDWA): Not regulated.

US state regulations

US. Massachusetts RTK – Substance List: Not regulated.

US. New Jersey Worker and Community Right-to-Know Act: Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law: Not listed.

US. Rhode Island RTK: Not regulated.

California Proposition 65: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

SECTION 16 - OTHER INFORMATION

Abbreviations:

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
CHAN	: Chemical Hazard Alert Notice
CHEMTREC	: Chemical Transportation Emergency Center
DOT	: Department of Transportation

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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
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

Data Sources: Information from published literature.

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