

Apollo Scientific

Part Number: **BISN0125** Version No: **1.1**

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Chemwatch Hazard Alert Code: 4

Issue Date: **12/03/2023**Print Date: **31/07/2023**S.REACH.GBR.EN

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

1.1. Product Identifier

Product name	Bortezomib
Chemical Name	bortezomib
Synonyms	Not Available
Proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Chemical formula	C19H25BN4O4
Other means of identification	Not Available
CAS number	179324-69-7*

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Use according to manufacturer's directions.
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Apollo Scientific
Address	Whitefield Road, Bredbury SK62QR United Kingdom
Telephone	01614060505
Fax	0161 406 0506
Website	http://www.apolloscientific.co.uk/
Email	sales@apolloscientific.co.uk

1.4. Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1] H310 - Acute Toxicity (Dermal) Category 2, H300 - Acute Toxicity (Oral) Category 2, H411 - Hazardous to the Aquatic Environment Long-Term Hazard Category 2, H318 - Serious Eye Damage/Eye Irritation Category 1, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H315 - Skin Corrosion/Irritation Category 2, H330 - Acute Toxicity (Inhalation) Category 2, H372 - Specific Target Organ Toxicity - Repeated Exposure Category 1

Issue Date: 12/03/2023 Print Date: 31/07/2023

Legend:

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

Hazard pictogram(s)









Signal word

Danger

Hazard statement(s)

H310	Fatal in contact with skin.
H300	Fatal if swallowed.
H411	Toxic to aquatic life with long lasting effects.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H315	Causes skin irritation.
H330	Fatal if inhaled.
H372	Causes damage to organs through prolonged or repeated exposure.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P260	Do not breathe dust/fume.
P262	Do not get in eyes, on skin, or on clothing.
P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P273	Avoid release to the environment.
P284	[In case of inadequate ventilation] wear respiratory protection.

Precautionary statement(s) Response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P330	Rinse mouth.
P361+P364	Take off immediately all contaminated clothing and wash it before reuse.
P302+P352	IF ON SKIN: Wash with plenty of water.
P391	Collect spillage.
P332+P313	If skin irritation occurs: Get medical advice/attention.

Precautionary statement(s) Storage

,,	
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.3. Other hazards

Inhalation and/or ingestion may produce serious health damage*.

Version No: 1.1 Bortezomib

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1.Substances

1. CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
Not Available	100	Bortezomib	Not Applicable	Not Applicable	Not Available

Page 3 of 14

Legend:

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

3.2.Mixtures

See 'Information on ingredients' in section 3.1

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: Immediately hold eyelids apart and flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. Transport to hospital or doctor without delay. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	 IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. For advice, contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise: INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. NOTE: Wear a protective glove when inducing vomiting by mechanical means.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

BASIC TREATMENT

Issue Date: 12/03/2023

Print Date: 31/07/2023

Part Number: BISN0125 Issue Date: 12/03/2023 Page 4 of 14 Print Date: 31/07/2023 Version No: 1.1 **Bortezomib**

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- Anticipate seizures.
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

ADVANCED TREATMENT

Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.

- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- ▶ Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- ► Treat seizures with diazepam.
- ▶ Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

SECTION 5 Firefighting measures

5.1. Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility

None known.

Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard.
	Wear breathing apparatus plus protective gloves in the event of a fire.
	Prevent, by any means available, spillage from entering drains or water courses.
	Use fire fighting procedures suitable for surrounding area.
	▶ DO NOT approach containers suspected to be hot.
	 Cool fire exposed containers with water spray from a protected location.
	If safe to do so, remove containers from path of fire.
	► Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	► Non combustible.
	Not considered a significant fire risk, however containers may burn.
	May emit poisonous fumes.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

	<u> </u>
Minor Spills	 Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal.
Major Spills	

6.4. Reference to other sections

Part Number: BISN0125 Page 5 of 14 Issue Date: 12/03/2023 Version No: 1.1 Print Date: 31/07/2023

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

- Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- ► When handling, **DO NOT** eat, drink or smoke. Safe handling
 - ▶ Keep containers securely sealed when not in use.
 - Avoid physical damage to containers.
 - Always wash hands with soap and water after handling.
 - ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.
 - Use good occupational work practice.
 - ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.
 - Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Fire and explosion protection

See section 5

Other information

- Store in original containers.
- Keep containers securely sealed.
- ▶ Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2. Conditions for safe storage, including any incompatibilities

- Lined metal can, lined metal pail/ can.
- Plastic pail.
- Polyliner drum.
- ▶ Packing as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):

- Removable head packaging:
- Cans with friction closures and
- low pressure tubes and cartridges

Suitable container

may be used.

Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages *.

In addition, where inner packagings are glass and contain liquids of packing group I and II there must be sufficient inert absorbent to absorb any spillage *.

* unless the outer packaging is a close fitting moulded plastic box and the substances are not incompatible with the plastic.

All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

Storage incompatibility

- None known
- Hygroscopic
- Light sensitive Moisture sensitive
- ► Store at-20°c
- Store under argon

Hazard categories in accordance with Regulation (EC) No 1272/2008

H2: Acute Toxic, E2: Hazardous to the Aquatic Environment in Category Chronic 2

Qualifying quantity (tonnes) of dangerous

H2 Lower- / Upper-tier requirements: 50 / 200 E2 Lower- / Upper-tier requirements: 200 / 500 : 1.1 Bortezomib

Issue Date: 12/03/2023 Print Date: 31/07/2023

substances as referred to in Article 3(10) for the application of

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Not Available	Not Available	Not Available

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available						

Not Applicable

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Bortezomib	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Bortezomib	Not Available	Not Available

8.2. Exposure controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.

Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection.

An approved self contained breathing apparatus (SCBA) may be required in some situations.

Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

8.2.1. Appropriate engineering controls

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents

 Part Number: BISN0125
 Page 7 of 14
 Issue Date: 12/03/2023

 Version No: 1.1
 Bortezomib
 Print Date: 31/07/2023

2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Individual protection measures, such as personal protective equipment













Eye and face protection

▶ Safety glasses with side shields

- ► Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

Skin protection

See Hand protection below

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- \cdot frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.

Hands/feet protection

· Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- · Excellent when breakthrough time > 480 min
- \cdot Good when breakthrough time > 20 min
- · Fair when breakthrough time < 20 min
- $\boldsymbol{\cdot}$ Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task. Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Wear chemical protective gloves, e.g. PVC.
- ► Wear safety footwear or safety gumboots, e.g. Rubber

Body protection

See Other protection below

Other protection

- Overalls.Evewash unit.
- ▶ Barrier cream.

Version No: 1.1

Bortezomib Print Date: 31/07/2023

Issue Date: 12/03/2023

Skin cleansing cream.

Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- · Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- · Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- · Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- · Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- · Use approved positive flow mask if significant quantities of dust becomes airborne.
- \cdot Try to avoid creating dust conditions.

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	122-124	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	1.214	VOC g/L	Not Available

Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Information on toxicological effects

Postorowih.	TOXICITY	IRRITATION			
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.				
Еуе	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.				
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.				
Ingestion	Accidental ingestion of the material may be seriously damaging to the health of the individual; animal experiments indicate that ingestion of less than 40 gram may be fatal.				
Inhaled	The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of dusts, generated by the material during the course of normal handling, may produce severe damage to the health of the individual. Relatively small amounts absorbed from the lungs may prove fatal.				
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Bortezomib	TOXICITY Not Available	IRRITATION Not Available		
Legend:	Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances			

Acute Toxicity	~	Carcinogenicity	×
Skin Irritation/Corrosion	~	Reproductivity	×
Serious Eye Damage/Irritation	~	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	~
Mutagenicity	×	Aspiration Hazard	×

Legend:

★ - Data either not available or does not fill the criteria for classification

✓ – Data available to make classification

11.2 Information on other hazards

Issue Date: **12/03/2023**Print Date: **31/07/2023**

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

Bortezomib	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air	
	No Data available for all ingredients	No Data available for all ingredients	

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

12.4. Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

12.5. Results of PBT and vPvB assessment

	Р	В	Т	
Relevant available data	Not Available	Not Available	Not Available	
PBT	×	×	×	
vPvB	×	×	×	
PBT Criteria fulfilled?				
vPvB			No	

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	 Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.
Waste treatment options	Not Available
Sewage disposal options	Not Available

Issue Date: 12/03/2023 Print Date: 31/07/2023

SECTION 14 Transport information

Labels Required



Marine Pollutant



2X

HAZCHEM

Land transport (ADR-RID)

14.1. UN number or ID number	2811	2811		
14.2. UN proper shipping name	TOXIC SOLID, OF	RGANIC, N.O.S		
14.3. Transport hazard	Class	6.1		
class(es)	Subsidiary risk	Not Applicab	le	
14.4. Packing group	II	11		
14.5. Environmental hazard	Environmentally ha	azardous		
	Hazard identifica	ation (Kemler)	60	
	Classification co	de	T2	
14.6. Special precautions	Hazard Label		6.1	
for user	Special provision	าร	274 614	
	Limited quantity		500 g	
	Tunnel Restriction	on Code	2 (D/E)	

Air transport (ICAO-IATA / DGR)

• •	•				
14.1. UN number	2811				
14.2. UN proper shipping name	Toxic solid, organic, n.o.s. *				
	ICAO/IATA Class 6.1				
14.3. Transport hazard class(es)	ICAO / IATA Subrisk	Not Applicable			
chaos(co)	ERG Code	6L			
14.4. Packing group	II				
14.5. Environmental hazard	Environmentally hazardous				
	Special provisions		A3 A5		
	Cargo Only Packing Ir	nstructions	676		
	Cargo Only Maximum	Qty / Pack	100 kg		
14.6. Special precautions for user	Passenger and Cargo	Packing Instructions	669		
	Passenger and Cargo	Maximum Qty / Pack	25 kg		
	Passenger and Cargo	Limited Quantity Packing Instructions	Y644		
	Passenger and Cargo Limited Maximum Qty / Pack		1 kg		

Sea transport (IMDG-Code / GGVSee)

14.1. UN number	2811

Version No: 1.1 **Bortezomib**

14.2. UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.		
14.3. Transport hazard	IMDG Class 6	6.1	
class(es)	IMDG Subrisk N	Not Applicable	
14.4. Packing group	П		
14.5. Environmental hazard	Marine Pollutant		
	EMS Number	F-A, S-A	
14.6. Special precautions for user	Special provisions	274	
101 4001	Limited Quantities	500 g	

Inland waterways transport (ADN)

2811				
TOXIC SOLID, ORGANIC, N.O.S.				
6.1 Not Applicable				
II .				
Environmentally hazardous				
Classification code	T2			
Special provisions	274; 614; 802			
Limited quantity	500 g			
Equipment required	EP			
Fire cones number	2			
	TOXIC SOLID, ORGANI 6.1 Not Applicable II Environmentally hazardo Classification code Special provisions Limited quantity Equipment required			

14.7. Maritime transport in bulk according to IMO instruments

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

14.7.3. Transport in bulk in accordance with the IGC Code

SECTION 15 Regulatory information

15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable -: Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

		-				
Seveso Category	H2, E2					

15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

ECHA SUMMARY

Not Applicable

National Inventory Status

Issue Date: 12/03/2023

Print Date: 31/07/2023

Part Number: BISN0125 Version No: 1.1 **Bortezomib** Issue Date: 12/03/2023 Print Date: 31/07/2023

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Not Available
Canada - DSL	Not Available
Canada - NDSL	Not Available
China - IECSC	Not Available
Europe - EINEC / ELINCS / NLP	Not Available
Japan - ENCS	Not Available
Korea - KECI	Not Available
New Zealand - NZIoC	Not Available
Philippines - PICCS	Not Available
USA - TSCA	Not Available
Taiwan - TCSI	Not Available
Mexico - INSQ	Not Available
Vietnam - NCI	Not Available
Russia - FBEPH	Not Available
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	12/03/2023
Initial Date	23/02/2023

Full text Risk and Hazard codes

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

PC - TWA: Permissible Concentration-Time Weighted Average

PC - STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit,

IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors

BEI: Biological Exposure Index

AIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List

Part Number: BISN0125 Version No: 1.1

Bortezomib

Issue Date: **12/03/2023**Print Date: **31/07/2023**

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification according to regulation (EC) No 1272/2008 [CLP] and	Classification Procedure
amendments Acute Toxicity (Dermal)	
Category 2, H310	Expert judgement
Acute Toxicity (Oral) Category 2, H300	Expert judgement
Hazardous to the Aquatic Environment Long-Term	Expert judgement
Hazard Category 2, H411	Export judgement
Serious Eye Damage/Eye Irritation Category 1, H318	Expert judgement
Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , H335	Expert judgement
Skin Corrosion/Irritation Category 2, H315	Expert judgement
Acute Toxicity (Inhalation) Category 2, H330	Expert judgement
Specific Target Organ Toxicity - Repeated Exposure Category 1, H372	Expert judgement

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