

PRODUCT AND COMPANY IDENTIFICATION

GHS Product Name: Bortezomib Product code: h-311 **Company:** PharmSintez.Lab Address: Skolkovo Nobel street, 5, Lab. 3a, 09. 556. Moscow, Russia Tel: +7 (495) 796-94-33 Fax: +7 (495) 796-94-33 Email: info@labphs.com

1.1 Product identifiers

Product name:	Bortezomib
Product Catalogue Number:	h-311
Band:	PharmSintez.Lab
CAS-No:	179324-69-7

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

		Identified uses:	Laboratory chemicals, Synthesis of substances.
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Section 2: HAZARDS IDENTIFICATION

Classification according to 67/548/EEC

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008 Acute toxicity - Oral Acute toxicity - Dermal Acute toxicity - Inhalation (Dusts/Mists) (H330) Specific target organ toxicity (repeated exposure) Category 1 -(H372)

Category 2 - (H300) Category 2 - (H310) Category 2 -

T+ - Very toxic Repr. cat. 2;R60 - Repr. cat. 2;R61 -T+;R26/27/28 - T;R48/23/24/25 - Xi;R36/38 -Xi;R41

2.2. Label Elements

Hazard symbols

R-code(s)

Contains Bortezomib Signal word Symbols/Pictograms

Hazard statements



H300 - Fatal if swallowed H310 - Fatal in contact with skin H372 - Causes damage to organs through prolonged or repeated exposure H330 - Fatal if inhaled

Precautionary Statements - EU (§28, 1272/2008) POISON P301 + P310 - IF SWALLOWED: Immediately call a

CENTER or doctor/physician P321 - Specific treatment (see Emergency Phone Number on this label) P280 - Wear eye protection/ face protection P361 - Remove/Take off immediately all contaminated clothing P322 - Specific measures (see Emergency Phone Number on this label) P310 - Immediately call a POISON CENTER or doctor/physician P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P403 + P233 - Store in a well-ventilated place. Keep container tightly closed P320 - Specific treatment is urgent (see Emergency Phone Number on this label) P260 - Do not breathe dust/fume/gas/mist/vapors/spray

2.3. Other Hazards General Hazards

Not applicable

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Molecular Weight	384.24
Formula	C19H25BN4O4

3.1 Substances

Chemical Name	EC No	CAS No	Weight %	Classification according to 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bortezomib	-	179324-	100	Xi:R36/38-41 T+;R26/27/28 T;R48/23/24/25- Repr.Cat.3;R62-63 Repr.Cat.2;R60-61	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1

Full text of R-phrases: see section 16 Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

	4.1.	Descri	ption	of	first	aid	measures
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General advice physician.	Immediate medical attention is required. If symptoms persist, call a	
Inhalation	Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mo to-mouth resuscitation. Move to fresh air in case of accidental inhalation of vapors. If symptoms persist, call a physician.	
Skin Contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Wash	
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Treat symptomatically.

4.2. Most important symptoms Symptoms	and effects, both acute and delayed No information available.
	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.
Self-protection of the first aider clothing.	
Solf protoction of the first eider	Never give anything by mouth to an unconscious person. Drink plenty of water. Clean mouth with water and drink afterwards plenty of water. Call a physician. Use personal protective equipment as required. Avoid contact with skin, eyes or
Ingestion	 lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately. Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. If symptoms persist, call a physician. Do NOT induce vomiting. Call a physician or poison control center immediately.
Eye contact	contaminated clothing before reuse. Wash off immediately with plenty of water. If skin irritation persists, call a physician. Immediately flush with plenty of water. After initial flushing, remove any contact

Section 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Note to physicians

for fire-fighters

Suitable Extinguishing MediaUse extinguishing measures that are appropriate to local circumstances and the
surrounding environment.5.2. Special hazards arising from
Specific hazards arising from
the chemical
Hazardous combustion productsUse extinguishing measures that are appropriate to local circumstances and the
surrounding environment.5.2. Special hazards arising from
the chemical
Hazardous combustion productsNo information available
Carbon oxides. Nitrogen oxides (NOx).5.3. Advice for firefighters
Special protective equipmentWear self-contained breathing apparatus and protective suit. Wear self contained

breathing apparatus for fire fighting if necessary.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required. Keep people away from and
spill/leak. Evacuate personnel to safe areas.
Use personal protection recommended in Section 8.
Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. See Section 12 for additional Ecological Information.
ntainment and cleaning up Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic
tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
Use personal protective equipment as required. Cover powder spill with plastic
to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly. Soak up with inert absorbent material. Dam up. Pick up and transfer to properly labeled containers. Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water. Take precautionary measures against static discharges.

6.4. Reference to other sections

See Section 12: ECOLOGICAL INFORMATION.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling required.	Avoid contact with skin, eyes or clothing. Use personal protective equipment as
	Wash contaminated clothing before reuse. Do not breathe
	dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product. Use with local exhaust ventilation.
	Corrosive hazard. Wear protective gloves/clothing and eye/face protection.
General Hygiene Considerations and	When using do not eat, drink or smoke. Regular cleaning of equipment, work area
	clothing is recommended. Avoid contact with skin, eyes or clothing. Wash hands thoroughly after handling. Keep away from food, drink and animal feeding stuffs.
7.2. Conditions for safe storage	. including any incompatibilities
Storage Conditions reach of	Keep container tightly closed in a dry and well-ventilated place. Keep out of the
	children. Keep containers tightly closed in a cool, well-ventilated place. Keep in properly labeled containers. Do not allow contact with air. Protect from moisture.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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8.1. Control parameters Exposure Limits occupational	This product, as supplied, does not contain any hazardous materials with
Derived No Effect Level (DNEL) Predicted No Effect Concentration (PNEC)	exposure limits established by the region specific regulatory bodies. No information available No information available.
8.2. Exposure controls	
Engineering Controls	Showers Eyewash stations Ventilation systems
Eye/face protection Skin and Body Protection clothing.	Tight sealing safety goggles. Face protection shield. Gloves made of plastic or rubber. Suitable protective clothing. Suitable protective
	Apron.
Respiratory protection	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State Appearance Odor	Solid No information available No information available
Property pH Melting point/freezing point	<u>Values</u> No information available 139 °C
Boiling point	684.30 °C
Flash point	No information available
Density	1.21 g/cm ³
Evaporation rate	No information available
Upper flammability limits	No information available
Lower flammability limit	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	2.00
Autoignition temperature	No information
available Decomposition temperatu	ure No information
available Kinematic viscosity	No information
available	
Explosive properties	No information available
Oxidizing properties	No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity Reactivity

Not applicable

10.2. Chemical stability

Stability Stable under recommended storage conditions. Sensitivity to Mechanical Impact No information available. Sensitivity to Static Discharge No information available.

10.3. Possibility of hazardous reactions

Hazardous polymerization No information available. Possibility of Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid

Do not allow contact with air. Exposure to air or moisture over prolonged periods.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous Decomposition Products Carbon oxides. Nitrogen oxides (NOx).

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity Product Information Information. Unknown acute toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	5.01 mg/kg
ATEmix (dermal)	50.01 mg/kg
ATEmix (inhalation-dust/mist)	0.05 mg/l

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity Ecotoxicity Unknown aquatic toxicity	May cause long lasting harmful effects to aquatic life. 100% of the mixture consists of components(s) of unknown hazards to the aquatic environment.	
12.2. Persistence and degradability Persistence and degradability No information available.		
12.3. Bioaccumulative potential Bioaccumulation	No information available.	
12.4. Mobility in soil Mobility	No information available.	
12.5. Results of PBT and vPvB assessment		

PBT and vPvB assessment	No information available.
12.6. Other adverse effects Other adverse effects	No information available

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products Disposal should be in accordance with applicable regional, national and local laws and regulations

	regulations.
Contaminated packaging	Do not reuse container.
Other Information	Waste codes should be assigned by the user based on the application for which the
product	
	was used.

Section 14: TRANSPORT INFORMATION

14.2 Proper shipping name
14.3 Hazard Class Subsidiary hazard class / Labels available
14.4 Packing Group
14.5 Environmental Hazard

14.6 Special Provisions

14.1 UN/ID no

RID / ADR UN3249 Medicine, solid, toxic, n.o.s. 6.1 No information

II Not applicable None Classification code T2 Tunnel restriction code (D/E) IMDG ICAO (air) / IATA UN3249 UN3249 Medicine, solid, Medicine, solid, toxic, toxic, n.o.s. n.o.s. 6.1 6.1 No information available No information available Ш Ш Not applicable Not applicable A3 221 EmS-No F-A, S-A

Section 15: REGULATORY INFORMATION

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

National Regulations

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

International Inventories All of the components in the product are on the following Inventory lists No information available

X - Listed

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances ENCS - Japan Existing and New Chemical Substances IECSC - China Inventory of Existing Chemical Substances KECL - Korean Existing and Evaluated Chemical Substances PICCS - Philippines Inventory of Chemicals and Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3	R61 - May cause harm to the unborn child R60 - May impair fertility R63 - Possible risk of harm to the unborn child R62 - Possible risk of impaired fertility R41 - Risk of serious damage to eyes R26/27/28 - Also very toxic by inhalation, in contact with skin and if swallowed R48/23/24/25 - Also toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed R23/24/25 - Also toxic by inhalation, in contact with skin and if swallowed R23/24/25 - Also toxic by inhalation, in contact with skin and if swallowed R36/38 - Irritating to eyes and skin
Full text of H-Statements referred to under sections 2 and	 H300 - Fatal if swallowed H310 - Fatal in contact with skin H330 - Fatal if inhaled H372 - Causes damage to organs through prolonged or repeated exposure if inhaled
Revision note	No information available.

Further information

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Version: 2.1 Revision Date: 12.09.2016 Print Date: 12.09.2016 information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The -information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Pharm-Sintez Lab and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

See <u>www.labphs.com</u> for additional terms and conditions of sale.

Preparation Information

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