

SAFETY DATA SHEET (SDS): According to the OSHA Hazard Communication Standard 29 CFR 1910.1200

## **SECTION 1. Identification**

### Product identifier

Product number 2204
Product name Bortezomib
UN number UN2811
Other means of identification 2204\$

#### Recommended use of the chemical and restrictions on use

**Identified uses**This product is intended for research purposes only.

**Uses advised against**This product is not intended for use in diagnostic procedures or therapeutics.

This product is not intended for use in humans or animals.

Manufacturer, importer, supplier

Manufacturer address Cell Signaling Technology, Inc.

3 Trask Lane Danvers, MA 01923 United States

TEL: +1 978 867 2300 FAX: +1 978 867 2400 www.cellsignal.com support@cellsignal.com

Company phone number 978-867-2300

Emergency telephone number In case of emergency call CHEMTREC 1-800-424-9300

## SECTION 2. Hazard(s) identification

## Classification

**Email address** 

Website

This substance/mixture is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute oral toxicity	Category 1
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1
Reproductive toxicity	Category 2
Specific target organ toxicity - repeated exposure (STOT RE)	Category 1

#### GHS Label elements, including precautionary statements



Signal Word Danger

## Hazard statement(s)

Fatal if swallowed Causes skin irritation

Causes serious eye damage

Suspected of damaging fertility or the unborn child

Causes damage to organs through prolonged or repeated exposure

#### Precautionary Statement(s)

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Do not breathe dust/fume/gas/mist/vapors/spray

IF exposed or concerned: Get medical advice/attention

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

IF ON SKIN: Wash with plenty of soap and water

If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash before reuse

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Immediately call a POISON CENTER or doctor/physician

Store locked up

Dispose of contents/container to an approved waste disposal plant

## Supplementary Hazard Information

Hazards not otherwise classified (HNOC) None

## **SECTION 3. Composition/information on ingredients**

 Formula
 C19H25BN4O4

 Molecular Weight
 384.24 g/mol

Chemical nature Monoconstituent substance

Synonyms Bortezomib;

Velcade®; PS-341; Boronic acid,

 $(3-methyl-1-((1-oxo-3-phenyl-2-((pyrazinylcarbonyl)amino)propyl)amino)butyl)-, (S-(R^*,S^*))-((1-oxo-3-phenyl-2-((pyrazinylcarbonyl)amino)propyl)amino)butyl)-, (S-(R^*,S^*))-((1-oxo-3-((pyrazinylcarbonyl)amino)propyl)amino)butyl)-, (S-(R^*,S^*))-((1-oxo-3-((pyrazinylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbonylcarbony$ 

Chemical Name	CAS No	Weight %
[(1R)-3-methyl-1-[[(2S)-3-phenyl-2-(pyrazine-2-carb	179324-69-7	100
onylamino)propanoyl]amino]butyl]boronic acid		

### **SECTION 4. First-aid measures**

Eye contact Rinse thoroughly with plenty of water, also under the eyelids. Keep eye wide open while

rinsing.

Skin contact Immediate medical attention is required. Wash off immediately with soap and plenty of

water removing all contaminated clothes and shoes. Remove and wash contaminated clothing before re-use. Wash off immediately with plenty of water. Immediate medical

attention is not required.

**Inhalation** Immediate medical attention is required. Move to fresh air. If not breathing, give artificial

respiration. Immediate medical attention is not required. IF INHALED: Remove to fresh air

and keep at rest in a position comfortable for breathing.

**Ingestion** Do NOT induce vomiting. Immediate medical attention is required. Never give anything by

mouth to an unconscious person. Drink plenty of water. Clean mouth with water. Do not

induce vomiting without medical advice. Consult a physician.

#### Most important symptoms and effects, both acute and delayed

Most commonly reported adverse reactions (incidence = 20%) in clinical studies include nausea, diarrhea, thrombocytopenia, neutropenia, peripheralneuropathy, fatigue, neuralgia, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia.

#### Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

#### Advice for emergency responders

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance. If symptoms persist, call a physician.

## **SECTION 5. Fire-fighting measures**

## **Extinguishing media**

surrounding environment.

Unsuitable Extinguishing Media CAUTION: Use of water spray when fighting fire may be inefficient.

## Specific hazards arising from the chemical

No information available.

#### **Explosion Data**

Sensitivity to Mechanical Impact None. Sensitivity to Static Discharge None.

#### **Protective Equipment and Precautions for Firefighters**

Wear self-contained breathing apparatus and protective suit. Wear self contained breathing apparatus for fire fighting if necessary.

#### SECTION 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Use personal protective equipment. Keep people away from and upwind of spill/leak.

Evacuate personnel to safe areas.

Other information No information available.

#### Environmental precautions

Do not flush into surface water or sanitary sewer system.

#### Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or

tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up

Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically and collect in suitable container for

spreading and keep powder dry. Take up mechanically and collect in suitable container for disposal. Avoid dust formation. Clean contaminated surface thoroughly. Soak up with inert absorbent material. Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water. Take precautionary measures against static

discharges.

## **SECTION 7. Handling and storage**

#### Precautions for safe handling

Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Prevent the formation of vapors, mists and aerosols. Do not eat, drink or smoke when using this product. Use only in area provided with appropriate exhaust ventilation.

## Conditions for safe storage, including any incompatibilities

Technical measures/Storage

Keep away from direct sunlight.

conditions

Packaging material

No information available.

**Incompatible products**None known based on information supplied.

## **SECTION 8. Exposure controls/personal protection**

#### Control parameters

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

## Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

### Individual protection measures, such as personal protective equipment

Personal protective equipment (PPE) needs to be selected depending on the implemented engineering controls, frequency/duration of work activities and the concentrations of the hazardous substance.

Eye/face protection
Skin and body protection

Tightly fitting safety goggles. Wear protective gloves/clothing.

Kin and body protection Wear protective gloves/clothing

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.

**Hygiene measures** When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area

and clothing. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Keep away from food, drink and animal feeding

stuffs.

## **SECTION 9. Physical and chemical properties**

## Information on basic physical and chemical properties

Physical state Solid Appearance Powder

Odor No information available
Color White to off-white
Odor Threshold No information available

**pH** 2-6.5 @ 0.0033 - 0.0038 g/L in water

Melting point/freezing point 124-140 °C

Initial boiling point and boiling No information available

range

Flash point
Evaporation rate
Flammability (solid, gas)
Upper flammability limit
Lower flammability limit
Vapor pressure
Vapor density
No information available.
No information available.
No information available.
No information available.
No information available

Relative density No information available

**Solubility** Partly soluble

Solubility in other solvents No information available

Partition coefficient: n-octanol/water2.0 estimated

Autoignition temperature
Decomposition temperature
Explosive properties
Oxidizing properties
No information available.
No information available
No information available

Molecular Weight 384.24 g/mol

VOC content
Viscosity
No information available
No information available.
No information available.

# **SECTION 10. Stability and reactivity**

## Reactivity

No information available.

## **Chemical stability**

Stable under recommended storage conditions.

#### Possibility of hazardous reactions

Hazardous reactions
Hazardous polymerization
None under normal processing.
None under normal processing.

#### **Conditions to Avoid**

No information available.

### **Incompatible Materials**

None known based on information supplied.

#### **Hazardous Decomposition Products**

None known based on information supplied.

## **SECTION 11. Toxicological information**

#### Information on likely routes of exposure

**Inhalation** May cause additional affects as listed under "Ingestion".

**Eve contact** May cause irreversible damage to eyes.

**Skin contact** Irritating to skin. May be harmful in contact with skin.

Ingestion Very toxic if swallowed. Target Organ Effects. Reproductive Toxicity.

## Information on toxicological effects

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxocological and physiological properties of this compound is not well defined.

## Delayed and immediate effects as well as chronic effects from short and long-term exposure

Symptoms Most commonly reported adverse reactions (incidence = 20%) in clinical studies include

nausea, diarrhea, thrombocytopenia, neutropenia, peripheralneuropathy, fatigue, neuralgia, anemia, leukopenia, constipation, vomiting, lymphopenia, rash, pyrexia, and anorexia.

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Skin corrosion/irritation Causes skin irritation.

Serious eve damage/eve

irritation

Sensitization

Risk of serious damage to eyes.

No information available. **Mutagenic effects** The weight of evidence demonstrates that this material is not genotoxic. Bortezomib

showed clastogenic activity (structural chromosomal aberrations) in the in vitro

chromosomal aberration assay using Chinese hamster ovary cells. Bortezomib was not genotoxic when tested in the in vitro mutagenicity assay (Ames test) and in vivo

micronucleus assav in mice.

No component of this product present at levels greater than or equal to 0.1% is identifiable Carcinogenicity

as probable, possible or confirmed carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity In a 6-month rat toxicity study, degenerative effects in the ovary were observed at doses =

> 0.3 mg/kg and degenerative changes in the testes occurred at 1.2 mg/kg. Pregnant rabbits given bortezomib during organogenesis at a dose of 0.05 mg/kg experienced significant post-implantation loss and decreased number of live fetuses. Live fetuses from these litters

also showed significant decreases in fetal weight.

STOT - single exposure

STOT - repeated exposure

In a repeat dose toxicity study in monkeys, myocardial hemorrhage, inflammation, and necrosis were observed. In animals, severe anemia and thrombocytopenia, and

gastrointestinal, neurological and lymphoid system toxicities were observed during chronic dosing. Neurotoxic effects of bortezomib included axonal swelling and degeneration in peripheral nerves, dorsal spinal roots, and tracts of the spinal cord, multifocal hemorrhage

and necrosis in the brain, eye, and heart.

Prolonged or repeated exposure increases the risk. Possible risks of irreversible effects. **Chronic Toxicity** 

Avoid repeated exposure.

No information available.

Cardiovascular system, Gastrointestinal tract (GI), Hematopoietic System, Central nervous **Target Organ Effects** 

system (CNS), Peripheral Nervous System (PNS).

**Neurological effects** No information available. No information available. **Aspiration Hazard** 

## **SECTION 12. Ecological information**

## **Ecotoxicity**

Product does not present an aquatic toxicity hazard based on known or supplied information.

Persistence and degradability No information available. Not likely to bioaccumulate. Bioaccumulation

**Mobility** Is predicted to have low mobility in the environment

Chemical Name	Octanol-Water Partition Coefficient
[(1R)-3-methyl-1-[[(2S)-3-phenyl-2-(pyrazine-2-carbonylamino)propanoyl]	2.0
amino]butyl]boronic acid	

## Other adverse effects

No information available.

## **SECTION 13. Disposal considerations**

## **Waste Disposal Methods**

Should not be released into the environment.

#### Disposal considerations

Do not empty into drains; dispose of this material and its container in a safe way.

## **SECTION 14. Transport information**

## DOT

UN number UN2811

**UN proper shipping name** Toxic solid, organic, n.o.s. (Bortezomib)

154

Transport hazard class(es)

Packing group

Special provisions IB7, T6, TP33

Emergency response guide

number

## IATA

UN number UN2811

**UN proper shipping name** Toxic solid, organic, n.o.s. (Bortezomib)

Transport hazard class(es) 6.1
Packing group I
ERG code 6L

## **SECTION 15. Regulatory information**

## **North American Inventory Listing**

Chemical Name	TSCA 8(b)	TSCA 12(b)	DSL	NDSL
[(1R)-3-methyl-1-[[(2S)-3-phenyl	Not Listed	Not Listed	Not Listed	Not Listed
-2-(pyrazine-2-carbonylamino)pr				
opanoyl]amino]butyl]boronic				
acid				

## Canadian Workplace Hazardous Materials Information System (WHMIS) Classification



Class D1A - Very Toxic Materials at >= 1% Class D2A - Very Toxic Material at >= 0.1%

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

## SARA 311/312 Hazard Categories

Acute Health Hazard Yes
Chronic Health Hazard Yes
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

## Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### California Proposition 65

This product does not contain any Proposition 65 chemicals.

## **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. FIFRA Label Information

This product does not contain any substances regulated as pesticides.

## US Commerce Department - Export Administration Regulations Information

This product does not contain any substances regulated under the Chemical Weapons Convention (CWC).

## U.S. Drug Enforcement Administration Information

This product does not contain any substances regulated under the DEA.

## **SECTION 16. Other information**

**Issuing Date:** 2014-05-20 **Revision Date:** 2015-01-22

**Disclaimer** 

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**