



300 Northfield Road
Bedford, OH 44146
Telephone: (800) 562-4797
-or- (440) 232-3320

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Pentostatin for Injection, 10mg/vial

Chemical Names: Imidazo(4,5-d)(1,3)diazepin-8-ol,3-(2-deoxy-beta-D-pentofuranosyl)-3,6,7,8-tetrahydro-,(R)-

Synonyms: Nipent®, Deoxycoformycin, CO-Vidarabine, (R)-3-(2-Deoxy-beta-D-pentofuranosyl)-3,6,7,8-tetrahydroimidazo(4,5-d)(1,3)diazepin-8-olCL 67310465, NSC-218321

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

Address: 300 NORTHFIELD ROAD
BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800) 424-9300

Telephone Number for Info.: (800) 562-4797 or (440) 232-3320

Medical Emergency: Professional Services 1(800) 521-5169

Date Prepared: February 12, 2007

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Pentostatin	97.5	53910-25-1	NONE	NONE	0.55 ug/m ³ (BVL OEL)
Mannitol	2.5	69-65-8	NONE	NONE	NONE

Pentostatin is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Pentostatin may be absorbed via inhalation, ingestion or skin or eye contact.

Health Hazard (Acute & Chronic): Pentostatin is a genotoxic and cytotoxic drug used in the treatment of hairy cell leukemia. It can produce a variety of systematic effects upon excess exposure such as to blood, liver, reproductive, and gastrointestinal systems. Chronic effects may cause toxicity to blood forming systems and block DNA/RNA synthesis. Pentostatin is a potential carcinogen, teratogen, and fetotoxin.

Carcinogenicity: NTP? NO IARC Monographs? NO OSHA Regulated? NO

Signs & Symptoms of Exposure: May cause changes in blood cell formation, nausea, vomiting, respiratory and skin irritations.

Medical Conditions Generally Aggravated by Exposure: Previously existing blood, liver, or gastrointestinal conditions. Persons with hypersensitivity to Pentostatin.

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin thoroughly with cool, soapy water.

Ingestion: If ingestion occurs, induce vomiting immediately and seek medical attention. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek the attention of a physician immediately. If necessary, provide artificial respiration. Overdose should be treated symptomatically and monitor blood chemistry.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not applicable

Flammable Limits: Not applicable **LEL:** Not applicable **UEL:** Not applicable

Extinguishing Media: Use water or multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters must wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to land: Lightly wet Pentostatin with water to prevent dusting. Wash areas exposed to Pentostatin with a 1% bleach solution. Follow by cleaning with soap and water. Wear personal protective equipment including nitrile or latex gloves. Dispose of sorbents in sealed containers and dispose of wastes properly in accordance with local, state, and federal regulations. Prevent contact with sewers and waterways.

Release to air: If dust is generated, reduce exposures by ventilating and prevent further generation of dust. Wear respiratory protection.

Release to water: Refer to local water authority; drain disposal is not recommended. Refer to federal, state and local guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear all necessary protective clothing, safety glasses and air-purifying respirator with HEPA filters (P100). Large spills require the use of self-contained breathing apparatus (SCBA).

Waste Disposal Method: Disposal via incineration is recommended. Follow federal, state and local regulations.

Precautions to be taken in handling and storing: Store at temperatures between 2-8°C (36-46°F).

Other Precautions: Follow OSHA guidelines on the safe handling of cytotoxic/genotoxic products (see Section XVI).

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use in a biological safety hood, respirators may not be

necessary. If dusts are generated and exposure levels exceeded, an air purifying respirator with HEPA filters (P100) must be worn. For large spills, SCBA may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

Ventilation: Use with adequate ventilation such as in a class II Type B biological safety hood.

Protective Gloves: Nitrile or latex (double layers)

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

Work/Hygienic Practices: No eating, drinking or smoking while handling this product. Use good personal hygiene.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid

Specific Gravity: Not applicable

Appearance and Odor: White powder with no odor

Melting Point: 220 - 225 °C

Boiling Point: Not applicable

Evaporation Rate: Not applicable

Vapor Pressure: Not applicable

Solubility in Water: Freely soluble

Vapor Density: Not applicable

pH (when reconstituted): 7.0 - 8.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable up to 40°C.

Incompatibility (Materials to Avoid): None identified.

Hazardous Decomposition or Byproducts: Decomposition products of Pentostatin may include oxides of carbon and nitrogen.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: None identified.

Section XI - TOXICOLOGICAL INFORMATION

For Pentostatin: RTECS # N12931000

LD₅₀ oral, mouse = 227 mg/kg

LD₅₀ intravenous, mouse = 122 mg/kg

Pentostatin has potential reproductive health risks as fetotoxic and teratogenic.

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is not currently available on the environmental impact of Pentostatin. Handle in a manner that prevents spills or release to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of via incineration according to federal, state and local guidelines.

Section XIV - TRANSPORTATION INFORMATION

This material is a DOT hazardous material according to 49 CFR 172.101

Proper Shipping Name: Medicine, solid, toxic, n.o.s., (Pentostatin)

Hazard Class and Description: 6.1 (Poisonous solid)

UN I.D. Number: NA 3249

Packing Group: III

DOT Labels required: Refer to CFR 173.4 (Small Quantity Exceptions)

Emergency Response Guide No.: 151

Pentostatin is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Massachusetts Hazardous Substance codes: NO

Pennsylvania Hazardous Substance code: NO

Minnesota Hazardous Substance codes: NO

California Proposition 65 code: D

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address the therapeutic use of this material
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company Management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2.= Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic

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