300 Northfield Road
Bedford, OH 44146
Telephone: (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Sterile Vinblastine Sulfate, USP
Chemical Names: Vincaleukoblastine Sulfate
Synonyms: Vinblastine
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
Medical Emergency: Professional Services: 1(800)521-5169
Date Prepared: June 6, 1996
Date Revised: December 28, 2001
Date Revised: July 20, 2007

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	%	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
Vincaleukoblastine Sulfate	100	143-67-9	NONE	NONE	0.3 - 0.5 mcg/m3

Vinblastine is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Bacteriostatic Sodium Chloride for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Vinblastine may be absorbed through the skin, ingested, or inhaled.
Health Hazard (Acute & Chronic): Vinblastine is a cytotoxic drug used to treat Hodgkin's Disease and cancers. It affects the central nervous system, digestive and blood forming systems, and will decrease immune cells in the blood and depress bone marrow. May cause allergic reactions in sensitive individuals. May cause cancer upon chronic exposures and secondary malignancies upon long-term exposure. Vinblastine is cytotoxic and a teratogen.
Carcinogenicity: **NTP?** NO **IARC Monographs?** Group III Inadequate human and animal evidence
OSHA Regulated? NO
Signs & Symptoms of Exposure: May cause irritation to eyes, skin, and respiratory system, nausea, vomiting, constipation, and mental depression. May cause allergic reaction symptoms

Medical Conditions Generally Aggravated by Exposure: May aggravate individuals who have central nervous system or digestive disorders.
BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 minutes.
Skin Exposure: Wash skin with cool, soapy water for 15 minutes; remove contaminated clothing.
Ingestion: If ingestion occurs, rinse mouth out with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting in an unconscious person.
Inhalation: Remove to fresh air. If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** NA **UEL:** NA
Flammable Limits: Not Applicable
Extinguishing Media: Use water or a type ABC multi-purpose extinguisher.
Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.
Unusual Fire/Explosion Hazards: Dry powder may be combustible

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Lightly wet Vinblastine powder and absorb with a damp absorbent cloth. Dispose according to local, state, and federal regulations.
Release to Air: If dust enters air, reduce exposures by ventilating the area; clean up the spill immediately.
Release to Water: Refer to the local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal 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 double latex or nitrile gloves, safety glasses, and an air-purifying respirator with HEPA (P100) cartridges. Large spills may require the use of SCBA.
Waste Disposal Method: Incineration in an approved/permitted incinerator is recommended. Refer to local, state, and federal guidelines.
Precautions to be taken in handling and storing: Store vials at 2-8°C, refrigerated.
Other Precautions: Handle carefully; follow OSHA guidelines for safe handling of cytotoxic products (see Section XVI).

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: If dust generation is possible, an air-purifying respirator with HEPA (P100) cartridges should be worn. 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 a Class II Type A Biological Safety Cabinet
Protective Gloves: Nitrile or latex
Eye Protection: Safety glasses or goggles
Other Protective Clothing or Equipment: Lab coat with closed front, long sleeves.
Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking when handling Vinblastine.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid
Specific Gravity: Not applicable
Appearance and Odor: White to off-white powder with no odor
Melting Point: 284°C
Boiling Point: Not applicable
Evaporation Rate: Not applicable
Vapor Pressure: Not applicable
Solubility in Water: Water soluble
Vapor Density: Not applicable

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable
Incompatibility (Materials to Avoid): oxidizers
Hazardous Decomposition or Byproducts: When heated to decomposition temperatures, toxic gases such as nitrogen oxides, carbon monoxide, carbon dioxide, and sulfur oxides may be created
Hazardous Polymerization: Will not occur
Conditions to Avoid: Storing with oxidizers

Section XI - TOXICOLOGICAL INFORMATION

For Vinblastine Sulfate: RTECS # YY8400000

LD_{50} mouse, intravenous = 9500 ug/kg	LD_{50} rat, intraperitoneal = 1 mg/kg
LD_{50} rat, oral = 305 mg/kg	LD_{50} rat, intravenous = 37 mg/kg
LD_{50} mouse, intraperitoneal = 2700 ug/kg	LD_{50} mouse, oral = 423 mg/kg
LD_{50} rat, subcutaneous = 355 mg/kg	LD_{50} mouse, subcutaneous = 324 mg/kg

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 currently not available on the environmental impact of Vinblastine. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of Sterile Vinblastine by incineration at an approved/permitted incinerator. Review local, state, and federal regulations for your regulatory area.

Section XIV - TRANSPORTATION INFORMATION

Sterile Vinblastine is not a DOT Hazardous Material.
Sterile Vinblastine is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
Listed on California's Proposition 65 List as Code D

Section XVI - OTHER DATA

1. Hospital personnel preparing or administering toxic parenteral agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all toxic or potent agents should be done in a Class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted this agent should be segregated for incineration.

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. Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.

4. 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

5. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

6. Vinblastine Sulfate is considered a Hazardous Drug as described in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.

7. **The Following Guidance Information is excerpted from the NIOSH Alert:**

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

8. **Published guidance on the handling and transport of cytotoxic drugs:**

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings
http://www.cdc.gov/niosh/docs/2004-165/

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:
http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm

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