



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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Vinorelbine Tartrate Injection (10 mg/mL; 1mL and 5 mL vials)
Chemical Names: C'-norvincal leukoblastine, 3'4', -dihydro-4'-deoxy-, (R-(R*,R*)) -2,3-dihydroxybutanedioate
Synonyms: NVB, Nor-5'-anhydrovinblastine, Navelbine Tartrate, Navelbine® Injection
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.: (440)232-3320 -or- (800)562-4797
Medical Emergency: Professional Services 1(800)521-5169
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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>
Vinorelbine Tartrate	1.0	125317-39-7	NONE	NONE	0.5 mcg/m3
Water for Injection	99.0	7732-18-5	NONE	NONE	NONE

Vinorelbine Tartrate Injection is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Contact with skin/eyes; inhalation of aerosols or accidental ingestion. Vinorelbine Tartrate Injection should be with supervision of a physician to control and monitor drugs side effects.

Health Hazard (Acute & Chronic): Vinorelbine Tartrate Injection is a genotoxic and cytotoxic drug generally used for the first-line treatment of non-small cell lung cancer (NSCLC). Adverse effects from exposure may include blood chemistry changes and effects to digestive and circulatory system. Vinorelbine Tartrate is fetotoxic and embryotoxic.

Medical Conditions Generally Aggravated by Exposure: Bone marrow toxicity specifically granulocytopenia, with increased susceptibility to infection.

Carcinogenicity: NTP? NO IARC Monographs? NONE OSHA Regulated? NO
 Vinorelbine Tartrate is a suspect Carcinogen.

Signs & Symptoms of Exposure: May cause severe irritation to skin, eyes, and respiratory tract. May cause nausea, vomiting, constipation, diarrhea, alopecia (hair loss), fatigue, shortness of breath, bronchospasm and chest pain. May cause allergic reactions.

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if irritation or signs of exposure are noted.

Skin Exposure: Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.

Injection: In cases of accidental injection, wash and disinfect area, get medical attention.

Inhalation: If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** Not Applicable **UEL:** Not Applicable

Flammable Limits: Not Applicable

Extinguishing Media: Use water or an 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. Product is aqueous-based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: Heat of the fire could cause vials to burst.

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Vinorelbine with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation

Release to Water: Refer to 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 latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Precautions to be taken in handling and storing: Store the vials under refrigeration at 2° to 8°C (36° to 46°F) in the carton. Protect from light. **DO NOT FREEZE.** Follow instructions provided in packaging.

Other Precautions: None Known

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: clear to pale yellow sol.

Boiling Point: Approx. 100°C

Vapor Pressure: Not available

Vapor Density: Not available

Specific Gravity: Approx. to water

Melting Point: Approx. 0°C

Evaporation Rate: Approx. to water

Solubility in Water: Soluble

pH: Not Available

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): water-reactive materials.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts including various oxides of carbon and nitrogen.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Storage near water reactive materials

Section XI - TOXICOLOGICAL INFORMATION

For Vinorelbine (active ingredient) RTECS Number RD2535000

LD₁₀ rat, Intravenous = 2 mg/kg and 11 mg/kg

LD₅₀ mice, Intraperitoneal = 78 mg/kg

LD₁₀ mice, Intravenous = 72 mg/kg

LD₅₀ rat, oral = 26 mg/kg

LD₅₀ male mice, oral = 77 mg/kg

LD₅₀ female rat, oral = 34 mg/kg

LD₅₀ female rat, intravenous = 12 mg/kg

LD₅₀ female mice, oral = 89 mg/kg

LD₅₀ female mice, intravenous = 42 mg/kg

Single intravenous doses of 1 or 2 mg/kg were lethal to Beagle dogs

Additional reproductive health 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

Vinorelbine Tartrate partitions to the aquatic compartment where it is likely to degrade when exposed to sunlight (photodegradation half-life = 9.07 hours) Vinorelbine is unlikely to bio-accumulate and has no toxicity to bacteria at environmental concentrations less than 1000 mg/L.

Section XIII - DISPOSAL INFORMATION

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

Section XIV - TRANSPORTATION INFORMATION

Vinorelbine Injection is not a DOT hazardous material.
Vinorelbine Injection is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
TSCA Listed?: YES

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address therapeutic use of this material.
2. Hospital personnel preparing or administering parenteral antineoplastic agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all antineoplastic 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.
3. 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.
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. Vinorelbine Tartrate may be 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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REFERENCES:

1. Registry of Toxic Effects of Chemical Substances, 11/2002
2. Physicians Desk Reference, On-Line PDR Electronic Library