



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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Cladribine 1mg/ml; 10ml/vial and 8ml/vial
Chemical Names: 2-chloro-2'-deoxy-adenosine
Synonyms: 2-CdA, 2-chlorodeoxyadenosine, Leustatin, NSC 105014-F, RWJ26251
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>
Cladribine	0.1	4291-63-8	NONE	NONE	2.5 mcg/m ³
Sodium Chloride	0.9	7647-14-S	NONE	NONE	NONE
Water for Injection	99.9	7732-18-5	NONE	NONE	NONE

Phosphoric Acid and Dibasic Sodium Phosphate for pH adjustment.
 Cladribine is a sterile injectable liquid drug provided in 10 or 8 mL vials.

Section III - HEALTH HAZARD DATA

Routes of Entry: Product may be absorbed via inhalation, ingestion or skin contact.
Health Hazard (Acute & Chronic): Product is an anticancer drug used for treating Hairy Cell Leukemia. It is a possible human teratogen. Cladribine may affect the digestive and central nervous systems. Product affects the blood forming systems, liver, and kidneys. Cladribine is fetotoxic.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO
Signs & Symptoms of Exposure: May cause irritation to eyes, skin and respiratory system or dermatitis to skin. May cause fatigue, nausea, vomiting and dizziness and a variety of other systemic effects.

Medical Conditions Generally Aggravated by Exposure: Medical conditions of the digestive and central nervous systems.

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large amounts of water for 15 minutes. Seek attention of a physician.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious and medical assistance is not available, induce vomiting. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary provide artificial respiration.

Overdose should be treated supportively and symptomatically. There is not a specific antidote.

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 a multi-purpose ABC 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 smoke inhalation. Product is aqueous-based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Cladribine with towels or absorbents and dispose of according to local, state, and federal regulations. Wear appropriate protective equipment. Prevent spills from entering drains or sewers. Wash area with soap and water.

Release to Air: If aerosolized, reduce exposures by ventilating area, clean spill immediately to prevent evaporation. Wear appropriate protective equipment.

Release to Water: Refer to local water authority. Drain disposal is not recommended.

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 up a spill. If aerosols are generated, a half-mask respirator with HEPA (P100) filters must be worn. For larger spills, additional clothing and respiratory protection may be needed such as chemical protective overalls, boots, double gloves, and self-contained breathing apparatus.

Waste Disposal Method: Incineration at an approved/permitted facility according to local, state, and federal guidelines.

Precautions to be taken in handling and storing: Store refrigerated 2° to 8°C (36° to 46°F). Protect from light during storage.

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators may not be required. If aerosols of product are generated, a half-mask respirator with HEPA (P100) cartridges may 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: Handle product in a biological safety hood or in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Necessary clothing to prevent skin contact such as a Lab coat with a closed front, long sleeves, or elastic cuffs.

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, colorless solution with no odor

Boiling Point: 100°C

Vapor Pressure: Approximate to water

Vapor Density: Approximate to water

Specific Gravity: Approximate to water

Melting Point: Not Applicable

Evaporation Rate: Approximate to water

Solubility in Water: Soluble

pH: 5.5 – 8.0

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Conditions to Avoid: Strong oxidizers or water reactive materials

Incompatibility (Materials to Avoid): Avoid storing next to oxidizers

Hazardous Decomposition or Byproducts: When heated, products of combustion may include nitrogen oxides, hydrogen chloride, carbon monoxide, and carbon dioxide.

Hazardous Polymerization: Will not occur

Section XI - TOXICOLOGICAL INFORMATION

Toxicity Data for Cladribine: RTECS # AU7357560

LD₅₀ mouse, intraperitoneal = 150 mg/kg

TD_{LO} monkey, intravenous = 7 mg/kg/7D-C

TD_{LO} human, man = 700 mg/kg/7D-C

TD_{LO} mouse, intraperitoneal = 100 mg/kg/5D-I

TD_{LO} rat, intraperitoneal = 40 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 Cladribine. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of via incineration at an approved/permitted waste disposal facility according to federal, state and local guidelines.

Section XIV - TRANSPORTATION INFORMATION

Cladribine is not a DOT Hazardous Material.
Cladribine is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO

Listed on California Proposition 65 List as Code D

Section XVI - OTHER DATA

1. 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.
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 the 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. Cladribine 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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