



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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Dexrazoxane Injection 250 and 500 mg/vial; 30 and 50 mL vials.

Chemical Names: 2,6-Piperazinedione, 4,4'-propylenedi-, (+)-

Synonyms: Cardioxane, ADR 529, ICRF-187, Zinecard®

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: December 22, 2004

Date Revised: July 24, 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>
Dexrazoxane	100	24584-09-6	NONE	NONE	54 ug/m ³ (BVL OEL)

Dexrazoxane is a sterile injectable drug presented as a powder cake. It must be reconstituted as directed with Sodium Lactate Injection. A 25 ml vial of Sodium Lactate Injection is provided to reconstitute a 250 mg vial of Dexrazoxane and a 50 ml vial for a 500 mg vial of Dexrazoxane.

Section III - HEALTH HAZARD DATA

Routes of Entry: Dexrazoxane Injection may be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Dexrazoxane Injection presents little hazard.

Health Hazard (Acute & Chronic): Dexrazoxane is used as a cardio-protective agent used in conjunction with Doxorubicin. It may affect the blood forming systems, liver, kidneys, and testes upon excessive quantities. It is poorly absorbed through the skin. Minimal health hazard is expected upon occupational exposure.

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

Signs & Symptoms of Exposure: Acute signs and symptoms of exposure may include eye, skin, and respiratory irritation. May cause loss of appetite and weight loss.

Medical Conditions Generally Aggravated by Exposure: Persons sensitive to Dexrazoxane may experience allergic reaction.

BVL Hazard Category: 3

BVL Occupational Exposure limit (OEL): 54 ug/m³

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 minutes or more. Seek treatment from a physician.

Skin Exposure: Wash skin with cool, soapy water. Remove contaminated clothing.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately.

If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek medical attention immediately.

If necessary, provide artificial respiration. Overdose should be treated symptomatically.

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 multi-purpose ABC extinguisher

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters 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: Wet Dexrazoxane with water and absorb with wipes/towels. Prevent contact with sewers and waterways. Wash area with soap and water. Wear personal protective equipment.

Release to Air: If dust is generated, reduce exposures by ventilating and preventing the generation of dusts. Wear respiratory protection.

Release to Water: Refer to the local water authority; drain disposal is not recommended. Refer to local, state, and federal 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 equipment including nitrile or latex gloves, protective clothing, safety glasses, and an air-purifying respirator with HEPA (P100) cartridges. Large spills may require the use of protective coveralls, boots, double gloves and SCBAs.

Waste Disposal Method: Dispose of according to local, state, and federal guidelines. Incineration at a licensed facility is recommended.

Precautions to be taken in handling and storing: Store at room temperature (15-25°C). Protect from light.

Other Precautions: None identified.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators should not be required if adequate ventilation is available. If dust generation is likely, air-purifying respirators with HEPA cartridge (P100) must be worn. For large spill emergencies, self-contained breathing apparatus (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: Handle product in a well-ventilated area.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: Lab coat

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

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid

Appearance and Odor: Whitish, no odor

Boiling Point: Not applicable

Vapor Pressure: Not applicable

Vapor Density: Not applicable

Specific Gravity: Not applicable

Melting Point: 191 - 197 °C

Evaporation Rate: Not applicable

Solubility in Water: Slightly soluble

pH (when reconstituted): 3.5 – 5.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid):

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and carbon dioxide.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: None identified.

Section XI - TOXICOLOGICAL INFORMATION

For Dexrazoxane: RTECS # TL6390000

LD₁₀, intraperitoneal, mouse = 500 mg/kg

LD₁₀, intravenous, dog = 2 gm/kg

TD₁₀ intravenous, man = 383 mg/kg

TD₁₀, intravenous, dog = 1250 mg/kg/5D-I

TD₁₀, intraperitoneal, rat = 100 mg/kg

Dexrazoxane was positive in genetic toxicity tests. Mutagenicity testing studies indicate Dexrazoxane was not Mutagenic in the Ames test but was found to be clastogenic to human lymphocytes *in vitro* and to mouse bone marrow erythrocytes *in vivo* (micronucleus test). It may cause fetal harm in pregnant women. 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 Dexrazoxane. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dexrazoxane should be disposed of in accordance with national, state, local, or applicable regulations. Incineration at an approved, permitted facility is recommended.

Section XIV - TRANSPORTATION INFORMATION

Dexrazoxane 20 mg/ml is not a DOT Hazardous Material.
Dexrazoxane is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: No
CERCLA listed?: No
RCRA listed?: No
TSCA listed: No

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
4. 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.
5. Dexrazoxane 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.
6. **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

7. **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>

This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this MSDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this MSDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product