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

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	%	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
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/m^3

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

$LD_{10,}$ intraperitoneal, mouse = 500 mg/kg
$LD_{lo,}$ intravenous, dog = 2 gm/kg
TD_{lo} intravenous, man = 383 mg/kg
$TD_{lo,}$ intravenous, dog = 1250 mg/kg/5D-I
$TD_{lo,}$ 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