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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Cerubidine® (Daunorubicin Hydrochloride for Injection)
20 mg/vial as lyophilized product
Chemical Names: 5,12-Naphthacenedione,8-acetyl-10-[(3-amino-2,3,6-trideoxy-a-L-lyxohexopyranosyl)]oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-,(8S-cis)-,hydrochloride
Synonyms: Daunoblastin; Daunomycin Hydrochloride; Daunomycin Chlorohydrate; Daunorubicin Hydrochloride; Acetyladriamycin, Leukaemomycin C, NCI-C04693, NSC-82151
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
Date Prepared: May 1, 1996
Date Revised: August 24, 2001
Date Revised: June 27, 2007

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	%	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
Daunorubicin Hydrochloride	18	23541-50-6	NONE	NONE	0.5 mcg/m3
Mannitol	82	69-65-8	NONE	NONE	NONE

Cerubidine® is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Rou Routes of Entry: Product may be absorbed by skin, eyes, inhalation, and ingestion.
Health Hazard (Acute & Chronic): Cerubidine® is a cytotoxic anticancer drug used to treat leukemias. Acute health effects upon excessive exposure may include irritation of eyes, skin, circulatory, and blood effects. May potentially effect the respiratory system. Product is corrosive to eyes, skin, and respiratory tract. Chronic exposure will produce effects similar to acute exposure. Dermatitis and allergic reaction are possible. Necrosis (death) of tissues can be observed on exposure to tissues at injection site (extravasation).

Carcinogenicity: **NTP?** NO **IARC Monographs?** YES (sufficient animal evidence) Group 2B
OSHA Regulated? NO

Cerubidine® may cause cancer and is possibly mutagenic and teratogenic.

Signs & Symptoms of Exposure: Nausea, vomiting, diarrhea, reversible hair loss, fever, chills, skin rash and possible allergic response, joint and back pain.

Medical Conditions Generally Aggravated by Exposure: Digestive tract and respiratory disorders.

BVL Hazard Category: **4**

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin with cool, soapy water.

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: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary, provide artificial respiration.
Treat overdose symptomatically. Monitor complete blood count and liver enzymes.

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 a water or multi-purpose ABC extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear a self contained breathing apparatus to avoid smoke inhalation.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wearing latex or nitrile gloves, wet Cerubidine® with water to prevent dusting and absorb with proper sorbents; dispose of sorbents in a sealed, labeled container. Prevent contact with sewers and waterways.

Release to Air: If dust is generated, reduce exposures by ventilating and prevent the generation of dust. Wear respiratory protection (air-purifying respirator with P100 HEPA Filters).

Release to Water: Refer to 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 air-purifying respirators with HEPA cartridges (P100). Large spills require the use of SCBA.

Waste Disposal Method: Dispose of Cerubidine® via incineration in accordance with local, state, and federal guidelines.

Precautions to be taken in handling and storing: Store at 15°-30°C; follow package insert.

Other Precautions: Follow OSHA guidelines for safe handling of cytotoxic products (see Section XVI).

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: If aerosols/dusts are generated, an air-purifying respirator (P100) with HEPA cartridges must 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 within a Class II Type B biological safety cabinet.
Protective Gloves: Nitrile or latex
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, and elastic cuffs.
Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking when handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid; powder
Appearance and Odor: Red with no odor
Boiling Point: Not Applicable
Vapor Pressure: Not Applicable
Vapor Density: Not Applicable
Specific Gravity: Not applicable
Melting Point: 188-190°C (Daunorubicin)
Evaporation Rate: Not Applicable
Solubility in Water: Water soluble
pH (of a 5mg/mL solution): 4.5 to 6.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable
Incompatibility (Materials to Avoid): Oxidizers
Hazardous Decomposition or Byproducts: Decomposition of this product may include potentially dangerous byproducts of nitrogen oxides, carbon monoxide, and carbon dioxide.
Hazardous Polymerization: Will not occur.
Conditions to Avoid: Storage with oxidizer

Section XI - TOXICOLOGICAL INFORMATION

For Daunomycin Hydrochloride: RTECS # HB7878000

LD_{50} oral, rat = 290 mg/kg
LD_{50} intraperitoneal, rat = 14,300 ug/kg
LD_{50} subcutaneous, rat = 33,200 ug/kg
LD_{50} intravenous, rat = 14,300 ug/kg
LD_{50} intravenous, mouse = 50 mg/kg
LD_{50} oral, mouse = 205 mg/kg
LD_{50} intraperitoneal, mouse = 3050 ug/kg
LD_{50} intravenous, mouse = 50 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 Cerubidine®. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted facility according to local, state, and federal regulations.

Section XIV - TRANSPORTATION INFORMATION

Cerubidine® is not a DOT hazardous material.
Cerubidine® is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
Cerubidine® is listed on the California Proposition 65 list as Code D

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. 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.

5. Cerubidine 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.

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