



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

**MATERIAL SAFETY DATA SHEET**

**Section I - IDENTITY**

**Common/Trade Name:** Daunorubicin Hydrochloride Injection 5mg/mL; 4mL and 10mL liquid filled vial

**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; Undena Cerubidine®

**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:** June 6, 1999

**Date Revised:** October 16, 2001

**Date Revised:** July 12, 2007

**Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION**

<u>Component</u>	<u>% (by weight)</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Daunorubicin					
Hydrochloride	0.5%	23541-50-6	NONE	NONE	NONE
Sodium Chloride	0.9%	7647-14-5	NONE	NONE	NONE
Water for Injection	98.6%	7732-18-5	NONE	NONE	NONE
Sodium Hydroxide and Hydrochloric Acid for pH adjustments					

Daunorubicin is a sterile injectable liquid drug provided in a vial.

**Section III - HEALTH HAZARD DATA**

**Routes of Entry:** Product may be absorbed by skin, eyes, inhalation, and ingestion.

**Health Hazard (Acute & Chronic):** Daunorubicin 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

Daunorubicin 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 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. Seek medical attention.

**Inhalation:** If difficulty breathing, administer oxygen. Seek attention of a physician immediately.

If necessary, provide artificial respiration.

Overdose should be treated symptomatically. Physician to monitor complete blood count.

#### Section V - FIRE AND EXPLOSION HAZARD DATA

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

**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, use sorbents to absorb spilled liquid. Take care to prevent generation of aerosols. Prevent contact with sewers and waterways. Dispose of sorbents in sealed container.

**Release to Air:** If aerosols are generated, reduce exposures by ventilating. Wear respiratory protection.

**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 Daunorubicin in accordance with local, state, and federal guidelines.

**Precautions to be taken in handling and storing:** Store at 2-8°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 aerosol generation is likely, an air-purifying respirator with HEPA Cartridges (P100) should 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:** Liquid

**Appearance and Odor:** Red with no odor

**Boiling Point:** Approximate to water

**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:** Water soluble

**pH:** 4.2 - 4.6

## 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 Daunorubicin Hydrochloride: RTECS # HB7878000

LD<sub>50</sub> oral, rat = 290 mg/kg

LD<sub>50</sub> interperitoneal, rat = 14,300 ug/kg

LD<sub>50</sub> subcutaneous, rat = 33,200 ug/kg

LD<sub>50</sub> intravenous, rat = 14,300 ug/kg

LD<sub>50</sub> oral, mouse = 205 mg/kg

LD<sub>50</sub> intramuscular, rat = 27,900 ug/kg

LD<sub>50</sub> subcutaneous, mouse = 28,800 ug/kg

LD<sub>50</sub> intramuscular, mouse = 23,300 ug/kg

LD<sub>50</sub> interperitoneal, mouse = 3,050 ug/kg

LD<sub>50</sub> 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 Daunorubicin. Handle in a manner to prevent 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

Daunorubicin Hydrochloride is not a D.O.T. hazardous material.  
Daunorubicin Hydrochloride is not a D.O.T. Marine Pollutant.

### Section XV - REGULATORY INFORMATION

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

### Section XVI - OTHER DATA

1. Hospital personnel preparing or administering toxic parenteral agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs, and respiratory protection. Preparation of all toxic or potent 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 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. Daunomycin Hydrochloride 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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