



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

## MATERIAL SAFETY DATA SHEET

### Section I - IDENTITY

**Common/Trade Name:** Doxorubicin Hydrochloride for Injection, USP (10mg, 20mg or 50mg/vial as lyophilized powder)

**Chemical Names:** 10-[(3-amino-2,3,6-trideoxy- $\alpha$ -L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-5,12-naphthacenedione

**Synonyms:** Doxorubicin Powder, Adriamycin®, ADM Hydrochloride, Adriacin, Adriablastina, FI 106, FI 6804, Hydroxydaunorubicin Hydrochloride, KW-125

**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.

**Address:** 300 NORTHFIELD ROAD  
 BEDFORD, OH 44146

**Emergency Telephone Number:** Chemtrec: 1(800)424-9300

**Medical Emergency:** Professional Services: 1(800)521-5169

**Telephone Number for Info.:** (440)232-3320 or (800)562-4797

**Date Prepared:** May 29, 1996

**Date Revised:** December 31, 2001

**Date Revised:** July 12, 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>
Doxorubicin					
Hydrochloride	16.6	25316-40-9	NONE	NONE	0.5 mcg/m <sup>3</sup>
Lactose Monohydrate	83.4	63-42-3	NONE	NONE	NONE

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

### Section III - HEALTH HAZARD DATA

**Routes of Entry:** This material may be harmful if swallowed or injected into the skin.

Exposure may occur via inhalation. This product is potentially corrosive to eyes, skin, and respiratory tract.

**Health Hazard (Acute & Chronic):** Doxorubicin is a cytotoxic drug used to treat a variety of cancers. May cause irritation to exposed tissues. Doxorubicin exposure may cause changes in blood chemistry and depression of bone marrow chemistry, digestive, and circulatory effects. May cause an allergic reaction.

**Carcinogenicity:** NTP? Yes, Group 2 IARC Monographs?: NO  
Reasonably anticipated to be a Human carcinogen  
**OSHA Regulated?** NO

Doxorubicin Hydrochloride is potentially carcinogenic fetotoxic, mutagenic, and teratogenic

**Signs & Symptoms of Exposure:** Nausea, vomiting, irritation of eyes, skin, and respiratory tract, loss of hair, loss of appetite, diarrhea, fever, chills, and allergic reaction may occur. May cause changes in skin pigmentation (especially in fingernail and toenail beds).

**Medical Conditions Generally Aggravated by Exposure:** Previously existing cardiovascular, liver, kidney, and bone marrow conditions.

**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, 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 attention of a physician immediately.

If necessary, provide artificial respiration.

If overdose occurs, treat symptomatically and monitor blood chemistry

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

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

**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 must use a (SCBA) self-contained breathing apparatus.

**Unusual Fire/Explosion Hazards:** None

#### Section VI - ACCIDENTAL RELEASE INFORMATION

**Release to Land:** Lightly wet Doxorubicin Powder to prevent dusting. Wearing latex or nitrile gloves, wipe up and dispose of wastes properly (in accordance with local, state, and federal regulations). Wash areas exposed to Doxorubicin with a 1% bleach solution. Dispose of sorbent in sealed containers.

**Release to Air:** If dust is in air, reduce exposures by ventilating area; clean up spills immediately and wear proper protective equipment.

**Release to Water:** Refer to local water authority. Drain disposal must not occur.

#### 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. If dusting occurs, wear a half mask respirator with HEPA cartridges (P100). For larger spills, additional protective clothing such as chemical protective coveralls, boots,

double gloves, and self-contained breathing apparatus (SCBA) may be needed.

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

**Precautions to be taken in handling and storing:** Store at room temperature 15-30°C. Protect from light.

**Other Precautions:** 1% bleach solutions may be used to decontaminate area of spill/release. Follow OSHA guidelines for safe handling of cytotoxic products (see Section XVI).

## Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

**Respiratory Protection:** Under normal use, respirators may not be required. If dusts of product are generated, a half-mask respirator with HEPA cartridges (P100) 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 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, and 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:** Solid

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

**Boiling Point:** Not applicable

**Vapor Pressure:** Not applicable

**Vapor Density:** Not applicable

**Specific Gravity:** Not applicable

**Melting Point:** 204-205°C

**Evaporation Rate:** Not applicable

**Solubility in Water:** Water soluble

## Section X - STABILITY AND REACTIVITY DATA

**Stability:** Stable

**Incompatibility (Materials to Avoid):** Oxidizers

**Hazardous Decomposition or Byproducts:** Products of combustion may include potentially hazardous byproducts of nitrogen oxides, hydrogen chloride, carbon monoxide, and carbon dioxide.

**Hazardous Polymerization:** Will not occur

**Conditions to Avoid:** Storage with oxidizers

## Section XI - TOXICOLOGICAL INFORMATION

For Doxorubicin Hydrochloride (active ingredient): RTECS # QI9295900

LD<sub>50</sub> rat, subcutaneous = 21840 ug/kg

LD<sub>50</sub> rat, intravenous = 12510 ug/kg

LD<sub>50</sub> mouse, oral = 698 mg/kg

LD<sub>50</sub> rat, intraperitoneal = 16030 ug/kg

LD<sub>50</sub> mouse, intraperitoneal = 11160 ug/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 Doxorubicin Hydrochloride.  
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**

Doxorubicin Hydrochloride for Injection is not a DOT Hazardous Material  
Doxorubicin Hydrochloride for Injection is not a Marine Pollutant.

## **Section XV - REGULATORY INFORMATION**

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Listed on Pennsylvania's Hazardous Substance list as Code S

## **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.
6. Doxorubicin Hydrochloride 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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