



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

**MATERIAL SAFETY DATA SHEET**

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**Section I - IDENTITY**

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**Common/Trade Name:** Doxorubicin Hydrochloride Injection, USP (2mg/mL; 5mL, 10mL, 25mL and 100mL)

**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 Solution, 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

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

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

**Date Prepared:** May 28, 1996

**Date Revised:** December 31, 2001

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

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<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Doxorubicin					
Hydrochloride	1	25316-40-9	NONE	NONE	0.5 mcg/m <sup>3</sup>
Sodium Chloride	0.9	7647-14-5	NONE	NONE	NONE
Water for Injection	98.1	7732-18-5	NONE	NONE	NONE
Hydrochloric Acid to adjust pH Preservative Free					

Doxorubicin Hydrochloride Injection is a sterile injectable liquid drug provided in a vial.

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**Section III - HEALTH HAZARD DATA**

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**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

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#### **Section IV - FIRST AID MEASURES**

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**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.

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

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**Flash Point (Method Used):** Not Applicable      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 should wear a self-contained breathing apparatus.

**Unusual Fire/Explosion Hazards:** None

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#### **Section VI - ACCIDENTAL RELEASE INFORMATION**

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**Release to Land:** Wearing latex or nitrile gloves, absorb Doxorubicin with absorbent wipes and dispose of in accordance with local, state, and federal regulations. Wash areas exposed to Doxorubicin with a 1% bleach solution.

**Release to Air:** If aerosolized, reduce exposures by ventilating the area; clean up spills immediately to prevent evaporation.

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

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#### **Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE**

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**Steps to be taken in case material is released or spilled:** See Section VI above; wear latex or nitrile gloves and safety glasses. If aerosols are generated, a half mask respirator with HEPA (P100) cartridges must be worn. For larger spills, additional clothing and respiratory protection may be needed such as chemical protective coveralls, boots, double gloves, and self-contained breathing apparatus (SCBA).

**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 under refrigeration at 2-8°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).

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## Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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**Respiratory Protection:** Under normal use, respirators may not be required. If aerosols of product are generated, a half-mask respirator with HEPA (P100) cartridges 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:** Use with adequate ventilation such as within a Class II Type B biological safety cabinet.

**Protective Gloves:** Latex or nitrile

**Eye Protection:** Safety glasses or splash 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.

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## Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

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**Physical State:** Liquid

**Appearance and Odor:** Clear, red with no odor

**Boiling Point:** 100°C

**Vapor Pressure:** Not applicable

**Solubility in Water:** Water soluble and miscible

**Specific Gravity:** 1.006

**Melting Point:** Not applicable

**Evaporation Rate:** Not available

**Vapor Density:** Not applicable

**pH:** 3

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## Section X - STABILITY AND REACTIVITY DATA

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**Stability:** Stable

**Incompatibility (Materials to Avoid):** Avoid storing next to oxidizers.

**Hazardous Decomposition or Byproducts:** When heated, products of combustion may include nitrogen oxides, hydrogen chloride, carbon monoxide and carbon dioxide.

**Hazardous Polymerization:** Will not occur

**Conditions to Avoid:** Strong oxidizer or water reactive materials

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## Section XI - TOXICOLOGICAL INFORMATION

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For Doxorubicin (the active drug substance)

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

LD<sub>50</sub> mouse, intraperitoneal = 11 mg/kg

LD<sub>50</sub> rat, intravenous = 13.1 mg/kg

LD<sub>50</sub> rat, subcutaneous = 21.8 mg/kg

LD<sub>50</sub> rat, intraperitoneal = 16 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).

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**Section XII - ENVIRONMENTAL IMPACT INFORMATION**

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Information is currently not available on the environmental impact of Doxorubicin Hydrochloride. Handle in a manner that prevents spills or releases to the environment.

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**Section XIII - DISPOSAL INFORMATION**

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Dispose of via incineration at an approved/permitted waste disposal facility according to federal, state, and local guidelines.

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**Section XIV - TRANSPORTATION INFORMATION**

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Doxorubicin liquid is not a DOT hazardous material.  
Doxorubicin liquid is not a Marine Pollutant.

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**Section XV - REGULATORY INFORMATION**

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SARA 313 listed?: NO  
CERCLA listed?: NO  
RCRA listed?: NO  
Listed on Pennsylvania's Hazardous Substance list as Code S

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**Section XVI - OTHER DATA**

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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.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.