



Material Safety Data Sheet

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Doxorubicin Hydrochloride Injection, USP
(2mg/mL; 25mL and 100mL)

Manufacturer 's Name : Sun Pharmaceutical Industries Limited

Address Sun Pharmaceutical Industries Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (E)
Mumbai – 400 059, INDIA

Trade names: Doxorubicin Hydrochloride Injection, USP

Note: This MSDS is written to provide health and safety information for personnel that will be handling the final product (i.e. transportation, distribution and health care workers). For health and safety information during manufacturing, refer to the appropriate MSDS of each component.

SECTION 2. PRODUCT COMPOSITION / HAZARDOUS INGREDIENTS

<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 ³
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.

SECTION 3. 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 4. 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 5. FIRE AND EXPLOSION HAZARD DATA

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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.

SECTION 7. 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 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).

SECTION 8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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

SECTION 10. STABILITY AND REACTIVITY DATA

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

SECTION 11. TOXICOLOGICAL INFORMATION

For Doxorubicin (the active drug substance): RTECS # QI9295900

LD50 mouse, oral = 570 mg/kg

LD50 mouse, intraperitoneal = 11160 ug/kg

LD50 rat, intravenous = 12510 ug/kg

LD50 rat, subcutaneous = 21840 ug/kg

LD50 rat, intraperitoneal = 16030 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 12. 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 13. DISPOSAL INFORMATION

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

SECTION 14. TRANSPORTATION INFORMATION

Doxorubicin liquid is not a DOT hazardous material.

Doxorubicin liquid is not a Marine Pollutant.

SECTION 15. REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Listed on Pennsylvania's Hazardous Substance list as Code S

SECTION 16. OTHER INFORMATION

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 :
 - 1 = Low Toxicity
 - 2 = Moderate Toxicity
 - 3 = Potent or Toxic
 - 4 = Highly Potent or Toxic
 - 5 = Extremely Potent or Toxic
5. 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.
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>

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