



Epirubicin Hydrochloride for Injection

Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V,
Gurgaon - 122 016, Haryana, INDIA

Section I - IDENTITY

Common/Trade Name: Epirubicin Hydrochloride for Injection (10mg/vial and 50mg/vial)

Chemical Names: 5,12-Naphthacenedione, 10-((3-amino-2,3,6-trideoxy-beta-L-arabino-hexopyranosyl)oxy)-7,8,9,10- tetrahydro-6,8,11-trihydroxy-8-(hydroxyacetyl)-1-methoxy-, (8S-cis)

Synonyms: Epiruba

Manufacturer's Name: GETWELL PHARMACEUTICALS

Address: 474, UDYOG VIHAR, PHASE-V,
GURGAON - 122 016, HARYANA, INDIA

Telephone Number for Info.: + 91 124 4014 403 / 04

Date Prepared: February 10, 2017

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>
Epirubicin					
Hydrochloride	0.2	56390-09-1	NONE	NONE	0.5 µg/m ³
Lactose Monohydrate	*	64044-51-5	NONE	NONE	NONE

Hydrochloric Acid is added for pH adjustment.

Epirubicin Hydrochloride for Injection is a sterile lyophilized drug provided glass vial.

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): Epirubicin is a genotoxic and cytotoxic drug used to treat breast and other cancers. It affects a variety of systems such as blood forming, circulatory, digestive, heart, liver and central nervous systems. Acute exposure may cause a wide variety of adverse effects including, nausea, vomiting, diarrhea, chills, fever, flu-like symptoms, irregular heartbeat, flushing of the skin, weight loss and allergic reaction. May cause irritation to eyes, skin and respiratory tract. May cause necrosis and damage to skin or tissues. Epirubicin exposure may cause changes in blood chemistry, bone marrow depression, digestive, and circulatory effects. Product may cause cancer and

secondary leukemia. May cause adverse effects in a developing fetus and is possibly teratogenic. Product is mutagenic.

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

Epirubicin Hydrochloride is potentially carcinogenic, mutagenic, fetotoxic, 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.

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 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 VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wearing latex or nitrile gloves, absorb Epirubicin with absorbent wipes and dispose of in accordance with local, state, and federal regulations. Wash areas exposed to Epirubicin 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 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 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 to 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 VIII - 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 IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Freeze dried Powder

Molecular Formula: Mixture

Section X - 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: Do not freeze.

Section XI - TOXICOLOGICAL INFORMATION

For Epirubicin Hydrochloride (the active drug substance): RTECS # QI9295840

LD₅₀ mouse, intravenous = 16,070 ug/kg

LD₅₀ rat, intravenous = 14,270ug/kg

LD₅₀ dog, intravenous = 2 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 Epirubicin 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

Epirubicin Hydrochloride liquid is not a DOT hazardous material.
Epirubicin Hydrochloride liquid is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

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

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. GP Hazard Category Definitions (internal hazard ranking used by Getwell Pharmaceuticals):
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 Getwell Pharmaceuticals 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. Epirubicin 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>

This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this MSDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this MSDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product