

# MATERIAL SAFETY DATA SHEET

## SECTION 1: COMPANY AND MATERIAL IDENTIFICATION

Supplier of Data Natco Pharma Limited  
Road No: 2, Banjara Hills,  
Hyderabad, India

Generic names: Doxorubicin HCl (liposome injection,  
Doxorubicin HCl [Pegylated liposomal]).

Note: This MSDS is written to provide health and safety information for personnel that will be handling the final product (i.e. transportation, distribution).

## SECTION 2: PRODUCT COMPOSITION

Component	CAS#	Formula	Percent
Doxorubicin Hydrochloride :.	.25316-40-9	C <sub>27</sub> H <sub>29</sub> NO <sub>11</sub> -HCl	0.2%
Liposomal carrier	not applicable	not applicable	99.8%

"Contains N-(carbonyl-methoxypolyethelene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine sodium salt (MPEG-DSPE), fully hydrogenated soy phosphatidylcholine (HSPC), cholesterol, ammonium sulfate, Histidine, sucrose and hydrochloric acid and/or sodium hydroxide for pH control.

## SECTION 2: HEALTH HAZARDS

### WARNING STATEMENT

CAUTION: Contains Doxorubicin Hydrochloride an antineoplastic agent used in chemotherapy. Doxorubicin Hydrochloride is a known carcinogen in animals and a probable carcinogen in humans. This drug is intended for human pharmaceutical use by intravenous infusion as prescribed by a physician.

## SECTION 3: HEALTH HAZARDS (CONTINUED)

Precautionary statement

Irritant: Irritating to eyes, skin and mucosa

Potential routes of exposure: Skin, eyes, ingestion, inhalation, accidental injection

Systemic:

Acute: Due to the nature of the use (intravenous infusion) of this drug no oral or inhalation toxicity data exists.

Chronic: Due to the nature of the use (intravenous infusion) of this drug no oral or inhalation toxicity data exists.

May cause reproductive and developmental toxicity. May cause carcinogenicity and mutagenicity. No toxicity data exists in humans.

#### Permissible Exposure Limit

No OSHA or ACGIH exposure limits have been set.

### **SECTION 4: FIRST AID MEASURES**

#### Eye contact

Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation develops seek medical **attention**.

#### Skin contact

Remove contaminated clothing and wash area thoroughly with soap and water for at least 15 minutes. Thoroughly wash with soap and water any garments that might have been contaminated before using again. If irritation develops seek medical **attention**.

#### Inhalation

Remove person to fresh air and notify emergency medical personnel.

#### Ingestion

Do not induce vomiting. Notify emergency medical personnel.

#### Accidental Injection

Seek medical attention.

### **SECTION 5: FIRE PROTECTION**

#### Extinguishing media

Water spray, carbon dioxide, dry chemical powder or foam

#### Special fire fighting procedures

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

If material is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment. Deny access to the spill area and minimize the spreading of the material. Be aware of broken glass. Carefully soak up any spilled material using Chemo-pads or other absorbent pads. Wipe area to remove as much of the liquid as possible. Apply bleach, or 5-6% sodium hypochlorite solution, to the affected area and let sit for at least two hours. Wipe the area down to remove the bleach and wash the area with soap and water. Collect all materials generated during the clean up in a suitable container and dispose of in accordance with the applicable local, state and federal waste disposal laws.

### **SECTION 7: HANDLING AND STORAGE**

Avoid contact with skin, eyes and mucosa. Wash thoroughly after handling.

Refrigerate at between 2°C and 8°C (36°F and 46°F).

## SECTION 8: EXPOSURE CONTROL

Wear latex gloves suitable for handling chemotherapy agents, safety goggles or glasses with side shields and a laboratory coat. Prepare syringes in a bio-safety cabinet or fume hood. Avoid generating aerosols when priming syringes.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Translucent liquid	% Volatile:	Not Available
Color:	Red	Evaporation:	Not Available
Odor:	Unknown	Melting Point:	Not Available
Boiling Point::	Not Available	Vapor Press.:	Not Available
Solubility in water:	Good '	pH:	6.5
Spec. Gravity:	1.03	Vapor Dens.:	Not Available

## SECTION 10: STABILITY AND REACTIVITY

Stability: Stable.

Hazardous combustion or decomposition products: Nature of decomposition products is not known.

Hazardous Polymerization: Will not occur

## SECTION 11: TOXICOLOGICAL INFORMATION

### Acute effects

May be harmful by inhalation and ingestion. Causes irritation to the skin and mucosa,

### Chronic effects

Confirmed carcinogenic, mutagenic and teratogenic in animal models. Probable carcinogenic, mutagenic and teratogenic in humans. Possible adverse effects on male and female fertility have not been adequately evaluated, but it is suspected that the effects are adverse to human fertility. RTECS data supplied is for the most abundant hazardous component of this product.

RTECS #019295900 — Doxorubicin Hydrochloride.

Only selected RTECS data is presented here. See actual entry in RTECS for complete information. Toxicity data

LD <sub>50</sub> :	21800' µg/Kg	subcutaneous — rat
LD <sub>50</sub> :	12510µg/Kg pglKg	intravenous — rat
LD <sub>50</sub> :	16 µg/Kg	intramuscular — rat
LD <sub>50</sub> :	698 µg/Kg	oral — mouse
LD <sub>50</sub> :	11160 pg/Kg	intraperitoneal— mouse
LD <sub>50</sub> :	7678 µg/Kg	subcutaneous - mouse
LD <sub>50</sub> :	1245 µg/Kg	intravenous — mouse
LD <sub>50</sub> :	13700 µg/Kg	intramuscular — mouse

