



## Doxorubicin Hydrochloride Liposome Injection

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### SECTION 1. COMPANY AND MATERIAL IDENTIFICATION

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Supplier of Data	Getwell Pharmaceuticals 474, Udyog Vihar, Phase-V, Gurgaon - 122 016, Haryana, INDIA
In case of emergency call:	+ 91 124 4014 403 / 04
Generic names:	Doxorubicin HCl liposome injection Doxorubicin HCl [ pegylated liposomal]
Trade names:	I-Dox <sup>®</sup> , Gedawell <sup>™</sup>
Date of Preparation	February 15, 2017

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.

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### SECTION 2. PRODUCT COMPOSITION

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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- ( carbamoyl-methoxypolyethelenc glycol 2000)- 1, 2- distearoyl-sn-glycero-3-phosphoethanolamine sodium salt( MPEG-DSPE), fully hydrogenated soy phophtidylcholine(HSPC), cholesterol, ammonium sulfata, histidine, sucrose and hydrochloric acid and/or sodium hydroxide for pH control.

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### SECTION 3. HEALTH HAZARDS

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#### 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.

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## **SECTION 3. HEALTH HAZARDS**

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### **Precautionary statement**

Irritant  
Irritating to eyes, skin and mucosa

### **Potential routes to 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.

### **Reproductive and Developmental Toxicity**

Doxorubicin HCl Liposome Injection is embryotoxic at doses of 1mg/kg/day (about 1/3 of the recommended human dose on mg/m<sup>2</sup> basis) in rats.

Doxorubicin HCl Liposome Injection is embryotoxic and abortifacient at 0.5mg/kg/day (about ¼ the recommended human dose on mg/m<sup>2</sup> basis) in rabbits. No data exists, for tests in humans, to confirm or deny the results of the animal models.

### **Carcinogenicity and Mutagenicity**

Although no studies have been conducted with Doxorubicin HCl Liposome Injection has been shown to have mutagenic and carcinogenic properties when tested in animal models. No data exists, for tests in humans, to confirm or deny the results of the animal models.

### **Permissible Exposure Limit**

No OSHA or ACGIH exposure limits have been set.

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## **SECTION 4. FIRST AID MEASURES**

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### **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.

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## **SECTION 4. FIRST AID MEASURES**

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### **Inhalation**

Remove person to fresh air and notify emergency medical personnel.

### **Ingestion**

Do not induce vomiting. Notify emergency medical personnel.

### **Accidental Injection**

In studies with rabbits, lesions that developed after subcutaneous injection of Doxorubicin HCl Liposome Injection were minor and reversible compared to the more severe and irreversible lesions and tissue necrosis that developed after subcutaneous injection of conventional doxorubicin HCl. Clean the puncture wound to prevent infection. Follow the local procedures concerning the possible exposure to blood borne pathogens, if needle was previously used. Seek medical attention.

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## **SECTION 5. FIRE PROTECTION**

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### **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.

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## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

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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.

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## **SECTION 7. HANDLING AND STORAGE**

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Avoid contact with skin, eyes and mucosa. Wash thoroughly after handling. Refrigerate at between 2° C and 8° C (36°F and 46°F).

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**SECTION 8. EXPOSURE CONTROL**

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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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

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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

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**SECTION 10. STABILITY AND REACTIVITY**

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**Stability**

Stable

**Hazardous combustion or decomposition products:**

Nature of decomposition products is not known.

**Hazardous Polymerization:**

Will not occur

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**SECTION 11. TOXICOLOGICAL INFORMATION**

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**Acute effects**

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

LDL <sub>0</sub> :	2571 µg/Kg/2Y	Intermittent intravenous –man
TDL <sub>0</sub> :	12mg/Kg/26W	Intermittent intravenous –man
LD <sub>50</sub> :	16030 µg/Kg	intraperitoneal – rat
LD <sub>50</sub> :	21800 µg/Kg	subcutaneous- rat
LD <sub>50</sub> :	12510 µg/Kg	intravenous -rat

LD <sub>50</sub> :	16 mg/Kg	intramuscular-rat
LD <sub>50</sub> :	698 mg/Kg	oral-mouse
LD <sub>50</sub> :	11160 µg/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
LD <sub>50</sub> :	6mg/Kg	intravenous –rabbit

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## SECTION 11. TOXICOLOGICAL INFORMATION

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Mutagenicity Data	[RTECS]
Carcinogenicity Data	[RTECS]
Reproductive Effects Data	[RTECS]

Target organs

Bone marrow, heart, immune system, reproductive system ( male)

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## SECTION 12. ECOLOGICAL INFORMATION

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Data not available

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## SECTION 13. DISPOSAL CONSIDERATIONS

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Mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Follow all local, state and federal Environmental, Health and Safety regulations.

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## SECTION 14. TRANSPORTATION INFORMATION

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Doxorubicin HCl Liposome Injection is not classified as a hazardous material according to regulations of the US Department of Transportation (49 CFR 173) nor the United Nations Recommendations on the Transport of Dangerous Goods.

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## SECTION 15. REGULATORY INFORMATION

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UN number:	Not listed
RID/ADR:	Not listed
EINECS:	Not listed (Doxorubicin HCl Liposome Injection is not listed. The active ingredient, doxorubicin hydrochloride, is listed as 246-818-3)
TSCA:	Not listed*
RCRA:	Not listed*
SARA(302):	Not listed*
SARA (313)	Not listed*
OSHA:	No exposure limits set*

\* Neither Doxorubicin HCl Liposome Injection nor its active ingredient, doxorubicin hydrochloride, is listed.

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**SECTION 16. OTHER INFORMATION**

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Getwell Pharmaceuticals shall not be held liable for any damage resulting from handling or from contact with the above product. See your invoice or packing slip for any additional terms and conditions.