Material Safety Data Sheet

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Doxorubicin HCl liposome Injection
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:	**LIPODOX**

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

COMPONENT	CAS#	FORMULA	PERCENT
Doxorubicin Hydrochloride	25316-40-9	C27H29NO11-HCl	0.2 %
Liposomal carrier*	not applicable	not applicable	99.8 %

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

SECTION 3. HAZARDS INFORMATION

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. HAZARDS INFORMATION (CONTINUED)

Precautionary statement:
Irritant : Irritating to eyes, skin and mucosa
Potential route 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 permissible exposure limits have been set.

SECTION 4. FIRST AID MEASURES

Inhalation

Remove person to fresh air and notify emergency medical personnel.

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.

Eye contact

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

Ingestion

Do not induce vomiting. Notify emergency medical personnel.

Accidental Injection

Seek Medical attention

SECTION 5. FIRE FIGHTING MEASURES

Extinguishing media

Water spray, carbon dioxide, dry chemical powder or foam.

Fire fighting procedures

As with all fires,evacuate Personnel to safe area. Firefighters should use self -contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCINDENTAL 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

Handling : Avoid contact with skin, eyes and mucosa. Wash thoroughly after handling.
Storage : Refrigerate at between 2°C and 8°C (26°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 Pressure:**	Not available
Solubility in water:	Good	**pH:**	6.5
Specific gravity:	1.03	**Vapor Density:**	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, eyes and mucosa.
Chronic effects: Confirmed Carcinogenic, mutagenic and teratogenic in animal models. Probable

SECTION 11. TOXICOLOGICAL INFORMATION (CONTINUED)

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_{50} (oral- mouse)	: 698 mg/kg.
LD_{50} (Intravenous-rat)	: 12510 µg/kg
LD_{50} (Intramuscular-rat)	: 16 µg/kg
LD_{50} (Subcutaneous-rat)	: 21800 µg/kg
LD_{50} (Intravenous-rabbit)	: 6 mg/kg

SECTION 12. ECOLOGICAL INFORMATION

No data is available regarding risks to waterways. Avoid that the product is discharged into waterways or drains which can contaminate groundwater.

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORTATION INFORMATION

Transport by road/rail: No restriction.
AIR transport: No restriction
Doxorubicin HCl liposome Injection (LIPODOX) 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.

SECTION 15. REGULATORY INFORMATION

UN number:	Not listed
RID/ADR:	Not listed
EINECS No.:	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 (LIPODOX®) nor its active ingredient, Doxorubicin Hydrochloride is listed.

SECTION 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. SUN Pharmaceutical Industries Limited, 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.