LUPIN PHARMACEITICALS INC.

SAFETY DATA SHEET

Section 1: Identification

Material	**Doxorubicin Hydrochloride Liposome Injection**
Manufacturer by	ForDoz Pharma Corporation 69 Princeton Hightstown Rd East Windsor, NJ 08520
Manufacturer for	Lupin Pharmaceuticals Inc. 5801 Pelican Bay Boulevard Suite 500 Naples, FL 340108
Recommended use of the chemical and restrictions on use	Finished Pharmaceutical Product Pharmacotherapeutic group: Cytostatic This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component. This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

Section 2: Hazard(s) Identification

GHS Classification

Acute toxicity	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1
Specific target organ toxicity - single exposure	Category 3
Carcinogenicity	Category 1B
Reproductive toxicity	Category 2

GHS Label element

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Hazard pictograms

Signal word: Danger

Hazard statements:

H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H350 May cause cancer. H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H335 May cause respiratory irritation.

Precautionary statements	**Prevention:** P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/ eye protection/ face protection. P271 Use only outdoors or in a well-ventilated area. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. **Response:** P310 Immediately call a POISON CENTER or doctor/ physician. P321 Specific treatment (see supplemental first aid instructions on this label). P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. P330 Rinse mouth. **Storage:** P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. **Disposal:** P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards	Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidently leaking, broken or crushed.
Chemical nature	Liquid

Section 3: Composition/Information on Ingredients

Substance / Mixture	Mixture
Chemical nature	Liquid

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
DOXORUBICIN HYDROCHLORIDE	25316-40-9	>= 0.1 - < 1

Section 4: First-Aid Measures

If inhaled	If breathed in, move person into fresh air. Consult a physician.
In case of skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water. If symptoms persist, call a physician. Wash contaminated clothing before re-use.
In case of eye contact	Rinse immediately with plenty of water, also under the eyelids for at least 15 minutes. Remove contact lenses. Consult a physician

If swallowed	Rinse mouth with water. Call a physician immediately.
Most important symptoms and effects, both acute and delayed	Ingestion may provoke the following symptoms: Harmful if swallowed. Danger of very serious irreversible effects. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
Notes to physician	Treat symptomatically. Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

Section 5: Fire-Fighting Measures

Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	Water spray jet
Hazardous combustion products	No hazardous combustion products are known
Further information	In the event of fire, cool tanks with water spray.
Special protective equipment for firefighters	In the event of fire, wear self-contained breathing apparatus.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Evacuate personnel to safe areas. In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Environmental precautions	Should not be released into the environment.
Methods and materials for containment and cleaning up	Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers. Small spills: Gently cover the spill with an absorbent towel or pad. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

Section 7: Handling and Storage

Advice on protection against fire and explosion	No data available
Advice on safe handling	To avoid thermal decomposition, do not overheat. For personal protection see section 8. Avoid inhalation, ingestion and contact with skin and eyes. Do not break, crush or spill this Finished Pharmaceutical Product.
Conditions for safe storage	To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well- ventilated place. Keep away from heat and sources of ignition. Keep locked up
Recommended storage temperature	2 - 8 °C

Section 8: Exposure Controls/Personal Protection

Components with workplace control parameters

Chemical Name	FORDOZ OEL
Doxorubicin hydrochloride	ForDoz OEL (8hr-TWA): 0.2 µg/m^3

Engineering measures	All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection	No personal respiratory protective equipment normally required. Engineering controls should always be the primary method of controlling exposures. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances pre- sent.

Hand protection

Remarks	Skin protection required for pregnant women or women of child bearing age. Gloves.
Skin and body protection	Preventive skin protection
Protective measures	The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult an Environmental Health and Safety expert if necessary.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.

Section 9: Physical and Chemical Properties

Appearance	Vial
Color	red
Odor	No data available
Odor Threshold	No data available
pH	No data available
Melting point/range	No data available
Boiling point/boiling range	No data available
Flash point	No data available
Upper explosion limit	No data available
Lower explosion limit	No data available
Vapour pressure	No data available
Relative vapour density	No data available
Relative density	No data available
Density	No data available
Solubility(ies)	No data available
Water solubility	
Partition coefficient: n- octanol/water	No data available
Decomposition temperature	No data available
Viscosity	No data available

Viscosity, dynamic	
Viscosity, kinematic	No data available
Explosive properties	No data available
Conductivity	No data available
Molecular weight	No data available

Section 10: Stability and Reactivity

Reactivity	None reasonably foreseeable.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	To avoid thermal decomposition, do not overheat. Incompatible materials
Incompatible materials	None known
Hazardous decomposition products	None known

Section 11: Toxicological Information

Acute toxicity
Product:

Acute oral toxicity	LD50 (Mouse): 698 mg/kg Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity	Remarks: No data available
Acute dermal toxicity	Remarks: No data available
Acute toxicity (other routes of administration)	Acute toxicity (other routes of administration)

Skin corrosion/irritation
Product:
Result: Skin irritation

Components:
DOXORUBICIN HYDROCHLORIDE
Remarks: No data available

Serious eye damage/eye irritation
Product:
Result: Corrosive to eyes

Components:
DOXORUBICIN HYDROCHLORIDE
Result: Eye irritation

Result: Lachrymation
Germ cell mutagenicity

Components:
DOXORUBICIN HYDROCHLORIDE

Genotoxicity in vitro	Remarks: No data available
Germ cell mutagenicity Assessment	Animal experiments showed mutagenic and teratogenic effects.

Carcinogenicity

Components:
DOXORUBICIN HYDROCHLORIDE
Remarks: carcinogenic effects

Carcinogenicity - Assessment	Sufficient evidence of carcinogenicity in animal experiments

IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. Group 3: Not classifiable as to its carcinogenicity to humans CHOLESTEROL 57-88-5
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Components:
DOXORUBICIN HYDROCHLORIDE

Effects on fertility	Remarks: No data available
Effects on foetal development	Species: Rat Remarks: Did show teratogenic effects in animal experiments.
Teratogenicity - Assessment	Potential embryo-foetal toxicity and teratogenicity., Limited evidence of adverse effects on development in animal studies and/ or human studies.

STOT - single exposure
Product:
Assessment: The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.
Components:
DOXORUBICIN HYDROCHLORIDE
Remarks: No data available

STOT - repeated exposure	Remarks: No data available

Repeated dose toxicity
Components:
DOXORUBICIN HYDROCHLORIDE
Remarks: No data available

Aspiration toxicity	No data available

Section 12: Ecological Information

Ecotoxicity

Components:
DOXORUBICIN HYDROCHLORIDE

Toxicity to fish	LC50 (Danio rerio (zebra fish)): 68 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 NOEC (Danio rerio (zebra fish)): 46 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	EC50 (Daphnia magna (Water flea)): 1.8 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No data available

	NOEC (Daphnia magna (Water flea)): 0.07 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	ErC50 (Pseudokirchneriella subcapitata (microalgae)): 11 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 Remarks: No data available NOECr (Pseudokirchneriella subcapitata (microalgae)): 1.9 mg/l Exposure time: 72 h Test Type: Growth inhibition Method: OECD Test Guideline 201 EbC50 (Pseudokirchneriella subcapitata (microalgae)): 4.1 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Method: OECD Test Guideline 201 NOECb (Pseudokirchneriella subcapitata (microalgae)): 1.9 mg/l Exposure time: 72 h Test Type: Cell multiplication inhibition test Method: OECD Test Guideline 201
Toxicity to bacteria	EC50 (activated sludge): > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 NOEC (activated sludge): 246 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Persistence and degradability	
Components: **DOXORUBICIN HYDROCHLORIDE**	
Bioaccumulation	Remarks: No data available
Partition coefficient: n- octanol/water	Remarks: No data available
Mobility in soil	No data available
Other adverse effects	
Product: Ozone-Depletion Potential	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Section 13: Disposal Considerations

Disposal methods Waste from residues	In accordance with National, Federal, State and Local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal

Section 14: Transport Information

International transport regulations

ADR
Not dangerous goods

RID
Not dangerous goods

DOT
Not dangerous goods

IATA
Not dangerous goods

IMDG
Not dangerous goods

Section 15: Regulatory Information

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

Massachusetts Right to Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

AMMONIUM SULFAAT	7783-20-2	0.1 - 1 %
DOXORUBICIN HYDROCHLORIDE	25316-40-9	0.1 - 1 %

California Prop 65	WARNING! This product contains a chemical known to the State of California to cause cancer. DOXORUBICIN HYDROCHLORIDE 25316-40-9 WARNING! This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. DOXORUBICIN HYDROCHLORIDE 25316-40-9
Other regulations	According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008. Restricted to professional users. This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

The components of this product are reported in the following inventories:

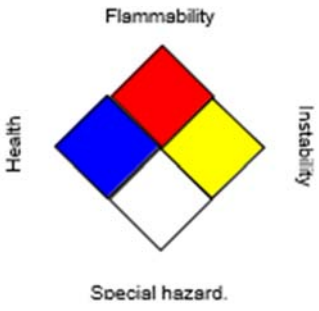
REACH	Not in compliance with the inventory CHOLESTEROL AMMONIUMSULFAAT 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol) (sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.
CH INV	Not in compliance with the inventory CHOLESTEROL AMMONIUMSULFAAT 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt)
TSCA	Not On TSCA Inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL. 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin
AICS	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin

NZIoC	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt)
ENCS	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin
ISHL	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE
KECI	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt)
PICCS	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin
IECSC	Not in compliance with the inventory 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol)(sodium salt) DOXORUBICIN HYDROCHLORIDE hydrogenated soybean lecithin

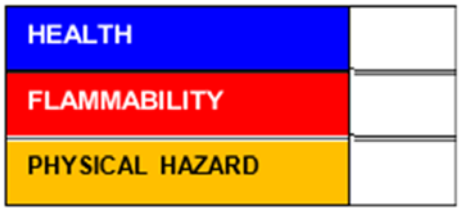
Section 16: Other Information

Further information

NFPA:



HMIS III:



0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

The information provided in this Safety Data Sheet is correct to the best of our knowledge, in- formation and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.