



1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Doxosome™-Doxorubicin Liposomes (PEGylated)
Product Number:	DOX-1000
Brand:	DOXOSOME™
Company Address:	ENCAPSULA NANOSCIENCES LLC 5409 Maryland Way, Suite 360 Brentwood, TN, 37027
Technical Phone:	615-884-4442
Fax:	615-250-8747
Emergency Phone:	615-438-8553

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	CAS#	Percent
Water	7732-18-5	>90
Sucrose	57-50-1	<5
Histidine	71-00-1	<5
Ammonium sulfate	7783-20-2	<5
L- α -phosphatidylcholine, hydrogenated	97281-48-6	<5
Cholesterol	57-88-5	<5
Doxorubicin hydrochloride	25316-40-9	<5
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-[methoxy(polyethylene glycol)-2000] (ammonium salt)	474922-77-5	<5

3. HAZARDS IDENTIFICATION

OSHA

Target Organ Effect, Harmful by Ingestion, Irritant, Carcinogen.

TARGET ORAGANS

Heart, Bone Marrow, Blood, Liver.

GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

Pictogram



Signal word: Danger

HAZARD STATEMENTS

H302 Harmful if Swallowed
H350 May cause cancer

PRECAUTIONARY STATEMENTS

P201 Obtain special instructions before use
P308, P313 If exposed or concerned: get medical advice and/or attention

HMIS RATING

HEALTH HAZARDS:	2
FLAMMABILITY:	0
CHRONIC HEALTH HAZARDS:	*
PHYSICAL HAZARDS:	0

NFPA RATING

HEALTH HAZARD:	2
FLAMMABILITY:	0
REACTIVITY:	0

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	May cause eye irritation.
Ingestion	May be harmful if swallowed.

4. FIRST AID MEASURES



ORAL EXPOSURE

Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.



INHALATION EXPOSURE

If inhaled, move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, oxygen. Consult a physician.



DERMAL EXPOSURE

In case of contact, immediately wash skin with soap and copious amounts of water. Contact a physician.



EYE EXPOSURE

In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes. Contact a physician.

5. FIRE FIGHTING MEASURES



FLAMMABILITY

Not flammable or combustible.

EXTINGUISHING MEDIA

It is suitable to use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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

HAZARDOUS COMBUSTION PRODUCTS

Hazardous decomposition products formed under fire conditions, carbon oxides, nitrogen oxides, sulphur oxides and hydrogen chloride gases.

6. ACCIDENTAL RELEASE MEASURES



METHODS FOR CLEANING UP

Absorb any spilled material quickly using absorbent pads. Wipe area to remove as much of the liquid as possible. Apply bleach to the affected area and let sit for several hours. Clean the affected area thoroughly with soap and water to remove the bleach. Collect all cleanup materials and dispose of them in accordance with local, state and federal waste disposal laws.

ENVIRONMENTAL PRECAUTIONS

Do not let product enter drains. If safe to do so prevent further leakages or spills.

PERSONAL PRECAUTIONS

Use personal protective equipment. Avoid breathing in vapors, mist or gas. Ensure adequate ventilation. Prepare evacuation sites.

7. HANDLING AND STORAGE



HANDLING

User Exposure: Do not breathe vapor. Do not get in eyes, on skin, on clothing. Wash hands thoroughly after handling.

STORAGE

Suitable: Keep in tightly closed container. Store in temperature between approximately 2-8 °C. Do not freeze. Product is sensitive to moisture and light.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION



ENGINEERING CONTROLS

Safety shower and eye bath. Mechanical exhaust required.

COMPONENTS WITH WORKPLACE CONTROL PARAMETERS

Contains no substances with occupational exposure limit values

PERSONAL PROTECTIVE EQUIPMENT

Respiratory: Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Where protection is desired, use full face respirator type N100 (US) or type P3 (EN 143) as back up to engineering controls.





Hand: Compatible chemical-resistant gloves

Eye: Chemical safety goggles with side shades conforming to EN166. Use equipment approved under government standards NIOSH (US) or EN 166(EU).

Skin and Body: Wear a complete suit protecting against chemicals.

GENERAL HYGIENE MEASURES

Wash hands thoroughly after handling. Wash contaminated clothing before reuse.
Prepare all materials under the fume hood and avoid generating aerosols.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Red translucent liquid
Safety data	pH 6.5
Melting point	N/A
Boiling point	N/A
Flash point	N/A
Ignition Temperature	N/A
Lower explosion limit	N/A
Upper Explosion limit	N/A
Water Solubility	N/A
Density	N/A

10. STABILITY AND REACTIVITY

STORAGE STABILITY

Store under recommended conditions.

MATERIALS TO AVOID

Strong oxidizing agents

HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products formed under fire conditions- Carbon oxides, nitrogen oxides, sulphur oxides and hydrogen chloride gases.

11. TOXICOLOGICAL INFORMATION

CARCINOGENICITY

This product contains a component that has been reported to be carcinogenic based on its IARC, OSHA, ACGIH, NTP, or EPA classification.

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 the IARC.

OSHA: 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 the OSHA.

ACGIH: 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 the ACGIH.

EPA: 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 the EPA.

ACUTE TOXICITY

Oral LD50- mouse rat-698 mg/kg,

Symptoms: Sense organs and special senses (eye-lacrimation; muscle weakness; diarrhea)

ROUTE OF EXPOSURE

<u>Skin Contact:</u>	May cause skin irritation. May cause harm if absorbed.
<u>Germ Cell Mutagenicity:</u>	N/A
<u>Eye Contact:</u>	May cause eye irritation
<u>Inhalation:</u>	Materials may be irritating to mucous membranes and upper respiratory tract.
<u>Ingestion:</u>	May cause harm if swallowed.

SIGNS AND SYMPTOMS OF EXPOSURE

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Elimination information (persistence and degradability)	N/A
Ecotoxicity effects	N/A
Further information on ecology	N/A

13. DISPOSAL CONSIDERATIONS

PRODUCT

Observe all federal, state, and local environment regulations. Contact a licensed professional waste disposal service to remove this material.

CONTAMINATED PACKAGING

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US) Not dangerous goods

IMDG Not dangerous goods

IATA Not dangerous goods

15. REGULATORY INFORMATION

OSHA HAZARDS

Target Organ Effect, Harmful by ingestion, Irritant, Carcinogen

SARA 302 COMPONENTS

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

SARA 313 COMPONENTS

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

SARA 311/312 HAZARDS

Acute health hazards, chronic health hazards

MASSACHUSETTS RIGHT TO KNOW COMPONENTS

	CAS-No.	Revision Date
Ammonium sulfate	7783-20-2	1993-04-24

PENNSYLVANIA RIGHT TO KNOW COMPONENTS

	CAS-No.	Revision Date
Water	7732-18-5	
Sucrose	57-50-1	
Histidine	71-00-1	
Ammonium sulfate	7783-20-2	1993-04-24
L- α -phosphatidylcholine, hydrogenated	97281-48-6	
Cholesterol	57-88-5	
Doxorubicin hydrochloride	25316-40-9	1989-08-11
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-[methoxy(polyethylene glycol)-2000] (ammonium salt)	474922-77-5	

NEW JERSEY RIGHT TO KNOW COMPONENTS

	CAS-No.	Revision Date
Water	7732-18-5	
Sucrose	57-50-1	
Histidine	71-00-1	
Ammonium sulfate	7783-20-2	1993-04-24
L- α -phosphatidylcholine, hydrogenated	97281-48-6	
Cholesterol	57-88-5	
Doxorubicin hydrochloride	25316-40-9	1989-08-11
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-[methoxy(polyethylene glycol)-2000] (ammonium salt)	474922-77-5	

CALIFORNIA PROP. 65 COMPONENTS

	CAS-No.	Revision Date
Doxorubicin hydrochloride	25316-40-9	1989-08-11

WARNING! This product is high product contains a chemical known to the state of California to cause cancer. 2008-06-17



Safety Data Sheet
Version 2.2
Revision Date: 03/21/2018

16. OTHER INFORMATION

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The above information is believed to be correct but does not support to be all inclusive and shall be used only as a guide.

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Encapsula NanoSciences LLC shall not be held liable for any damage resulting from handling or from contact with the above product.