

Version 2.2

Revision Date: 03/21/2018

# 1. PPRODUCT AND COMPANY IDENTIFICATION

Product Name: Doxosome™ Control-Doxorubicin Liposomes (PEGylated)

Product Number: DOX-2000

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
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N- [methoxy(polyethylene glycol)-2000] (ammonium salt)	474922-77-5	<5

# 3. HAZARDS IDENTIFICATION

### **OSHA**

No known OSHA hazards.

# GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

Not a hazardous substance or mixture.



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### **HMIS RATING**

HEALTH HAZARDS: 0
FLAMMABILITY: 0
CHRONIC HEALTH HAZARDS: 0
PHYSICAL HAZARDS: 0

### **NFPA RATING**

HEALTH HAZARD: 0
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.



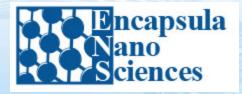
### **DERMAL EXPOSURE**

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.



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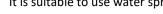
# 5. FIRE FIGHTING MEASURES

#### **FLAMMABILITY**

Not flammable or combustible.

### **EXTINGUISHING MEDIA**

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



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

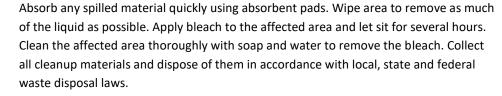
#### HAZARDOUS COMBUSTION PRODUCTS

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hazardous decomposition products formed under fire conditions, carbon oxides.

# 6. ACCIDENTAL RELEASE MEASURES

### **METHODS FOR CLEANING UP**





## **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.



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# 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



<u>Respiratory:</u> 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

<u>Eye</u>: 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.

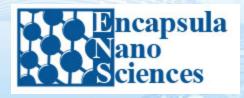


#### **GENERAL HYGIENE MEASURES**

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	White translucent liquid
Safety data	pH 6.5
Melting point	N/A
<b>Boiling point</b>	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



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# 10. STABILITY AND REACTIVITY

### STORAGE STABILITY

Store under recommended conditions. At 4 °C in refrigerator.

### **MATERIALS TO AVOID**

Strong oxidizing agents

#### HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous decomposition products formed under fire conditions; carbon oxides, nitrogen oxides, hydrogen chloride gas, sodium oxides and oxides of phosphorus.

#### **CONDITIONS TO AVOID**

Light and exposure to moisture.

# 11. TOXICOLOGICAL INFORMATION

<u>IARC:</u> 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.

<u>OHSA:</u> 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 OHSA.

**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**

No information available

### **ROUTE OF EXPOSURE**

Skin Contact: May cause skin irritation

Skin Absorption: May be harmful if absorbed through the skin

**Eye Contact**: May cause eye irritation

<u>Inhalation</u>: Materials may be irritating to mucous membranes and upper respiratory tract.

<u>Ingestion</u>: May be harmful if swallowed



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# 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. Dissolve or mix the material with a combustible solvent and burn chemical in incinerator equipped with an afterburner and scrubber.

#### **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

#### **SARA 302 COMPONENTS**

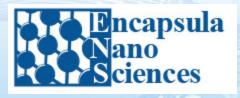
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302

### **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**

No SARA hazards



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# MASSACHUSETTS RIGHT TO KNOW COMPONENTS

This product does not contain any chemicals known to the state of MA to cause cancer, birth, or other reproductive defects.

### 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	
L-α-phosphatidylcholine, hydrogenated	97281-48-6	
Cholesterol	57-88-5	
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	
L-α-phosphatidylcholine, hydrogenated	97281-48-6	
Cholesterol	57-88-5	
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-	474922-77-5	
[methoxy(polyethylene glycol)-2000] (ammonium salt)		

# **CALIFORNIA PROP. 65 COMPONENTS**

This product does not contain any chemicals known to the state of CA to cause cancer, birth, or other reproductive defects.



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# **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.