

## 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Standard Doxosome™ Kit-Doxorubicin Liposomes (PEGylated) (Vial 1 of 2)
Product Number:	DOX-3000
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- $\alpha$ -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

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**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

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**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

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### 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

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### 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

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### 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

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

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

## 13. DISPOSAL CONSIDERATIONS

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### 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

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**DOT (US)** Not dangerous goods

**IMDG** Not dangerous goods

**IATA** Not dangerous goods

## 15. REGULATORY INFORMATION

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### 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- $\alpha$ -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- $\alpha$ -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

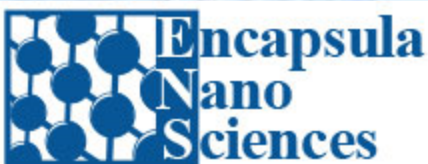
## 16. OTHER INFORMATION

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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.



## 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Standard Doxosome™ Kit-Doxorubicin Liposomes (PEGylated) (Vial 2 of 2)
Product Number:	DOX-3000
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- $\alpha$ -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.

**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.

## 5. FIRE FIGHTING MEASURES

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### **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.

## 6. ACCIDENTAL RELEASE MEASURES

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### **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

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### **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

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



## 10. STABILITY AND REACTIVITY

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### 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

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**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.

**OHSA:** 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

<u>Skin Contact:</u>	May cause skin irritation
<u>Skin Absorption:</u>	May be harmful if absorbed through the skin
<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 be harmful if swallowed

## 12. ECOLOGICAL INFORMATION

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

## 13. DISPOSAL CONSIDERATIONS

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### 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

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**DOT (US)** Not dangerous goods

**IMDG** Not dangerous goods

**IATA** Not dangerous goods

## 15. REGULATORY INFORMATION

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### 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

**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- $\alpha$ -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- $\alpha$ -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	

**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.



**Safety Data Sheet**  
Version 2.2  
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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.