

Version 2.2

Revision Date: 03/21/2018

# 1. PPRODUCT AND COMPANY IDENTIFICATION

Product Name: Immunodox®-Amine (PEGylated)

Product Number: IMD-1007

Brand: IMMUNODOX®

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

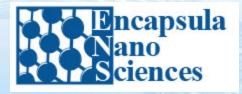
# 2. COMPOSITION/INFORMATION ON INGREDIENTS

gredient Name	CAS#	Percent
Vater	7732-18-5	>90
Sodium chloride	7647-14-5	<5
Potassium chloride	7447-40-7	<5
Disodium phosphate	7558-79-4	<5
Potassium phosphate	7758-11-4	<5
ammonium sulfate	7783-20-2	<5
Doxorubicin hydrochloride	25316-40-9	<5
-α-phosphatidylcholine, hydrogenated	97281-48-6	<5
Cholesterol	57-88-5	<5
.,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-methoxy(polyethylene glycol)-2000] (ammonium salt)	474922-77-5	<5
.,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-amino(polyethylene glycol)-2000] (ammonium salt)	N/A	<5

# 3. HAZARDS IDENTIFICATION

# GHS CLASSIFICATIONS IN ACCORDANCE WITH 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Eye irritation (Category 2A), H319 Carcinogenicity (Category 1B), H350



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# GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

Pictogram



Signal word: Danger

#### **HAZARD STATEMENTS**

Acute Tox. Acute toxicity
Carc. Carcinogenicity
Eye Irrit. Eye irritation

H302Harmful if SwallowedH350May cause cancerH315Causes skin irritation

**H319** Causes serious eye irritation

**Skin Irrit.** Skin irritation

#### **PRECAUTIONARY STATEMENTS**

**P201** Obtain special instructions before use

**P202** Do not handle until all safety precautions have been read

P264 Wash skin after handling

P270 Do not consume food or drink or indulge in smoking while using this product

P280 Wear protective gear when handling
P301, P312 If swallowed call poison center
P302, P352 If on skin wash skin thoroughly
P305, P351, P338 If in eyes rinse thoroughly

P308, P313 If exposed or concerned: get medical advice and/or attention

P321 Specific treatment P330 Rinse mouth

P332, P313 If skin irritation occurs get medical advice
P337, P313 If eye irritation occurs get medical advice

P362 Take off contaminated clothes and wash before reuse

P405 Store in lock up

**P501** Dispose of contents in waste disposal plant



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#### **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.



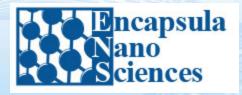
# **DERMAL EXPOSURE**

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.



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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.

#### 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 and sulphur oxides.

# **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

<u>Suitable:</u> Keep in tightly closed container. Store in temperature between approximately 2-8 ° C. Do not freeze.



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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





<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.



# **FULL CONTACT**

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

#### **SPLASH CONTACT**

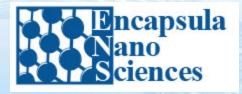
Material: Nitrile rubber

Minimum layer thickness: 0.11 mm Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

## **GENERAL HYGIENE MEASURES**

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



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# 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** Red translucent liquid Safety data pH 7.4 **Melting point** N/A **Boiling point** N/A Flash point N/A **Ignition Temperature** N/A Lower explosion limit N/A N/A **Upper Explosion limit Water Solubility** N/A Density N/A

# **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, sulphur oxides.

# 11. TOXICOLOGICAL INFORMATION

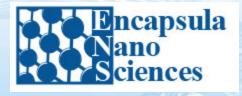
This product contains a component that has been reported to be carcinogenic based on its IARC, OHSA, ACGIH, NTP, or EPA classification.

<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.



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#### **ACUTE TOXICITY**

Oral LD50- mouse rat-698 mg/kg,

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

#### **ROUTE OF EXPOSURE**

Skin Contact: May cause skin irritation. May cause harm if absorbed.

Germ Cell Mutagenicity: N/A

**Eye Contact**: May cause eye irritation

<u>Inhalation</u>: Can cause respiratory tract irritation if inhaled.

<u>Ingestion</u>: May cause harm if swallowed.

#### SIGNS AND SYMPTOMS OF EXPOSURE

Dehydration, congestion, vomiting, or diarrhea may occur. May also produce inflammatory reactions in the gastrointestinal tract.

#### CARCINOGENICITY

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

REPRODUCTIVE TOXICITY N/A

SPECIFIC TARGET ORGAN TOXICITY- SINGLE OR REPEATED N/A

ASPIRATION HAZARDS N/A

#### **ADDITIONAL INFORMATION**

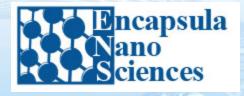
RTECS Q19295900

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

LIVER- Irregularities based on human evidence

# 12. ECOLOGICAL INFORMATION

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



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## 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**

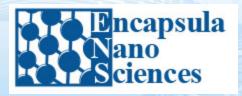
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed threshold (De Minimis) reporting levels established by SARA Title III, Section 313

# SARA 311/312 HAZARDS

Acute health hazards, chronic health hazards

#### MASSACHUSETTS RIGHT TO KNOW COMPONENTS

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



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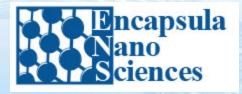
	CAS-No.	Revision Date
Makan	7722.40.5	
Water	7732-18-5	
Sodium chloride	7647-14-5	
Potassium chloride	7447-40-7	
Disodium phosphate	7558-79-4	
Potassium phosphate	7758-11-4	
Ammonium sulfate	7783-20-2	1993-04-24
Doxorubicin hydrochloride	25316-40-9	1989-08-11
L-α-phosphatidylcholine, hydrogenated	97281-48-6	
Cholesterol	57-88-5	
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-	474922-77-5	
[methoxy(polyethylene glycol)-2000] (ammonium salt)		
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-	N/A	
[amino(polyethylene glycol)-2000] (ammonium salt)		

#### NEW JERSEY RIGHT TO KNOW COMPONENTS

	CAS-No.	Revision Date
Water	7732-18-5	
Sodium chloride	7647-14-5	
Potassium chloride	7447-40-7	
Disodium phosphate	7558-79-4	
Potassium phosphate	7758-11-4	
Ammonium sulfate	7783-20-2	1993-04-24
Doxorubicin hydrochloride	25316-40-9	1989-08-11
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)		
1,2-distearoyl-sn-glycero-3-phosphoethanolamine-N-	N/A	
[amino(polyethylene glycol)-2000] (ammonium salt)		

# **CALIFORNIA PROP. 65 COMPONENTS**

CALIFORNIA I NOT: 05 CONIT ONE NTS	CAS-No.	Revision Date
Doxorubicin hydrochloride	25316-40-9	1989-08-11



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

**WARNING!** This product is high product contains a chemical known to the state of California to cause birth defects or other reproductive harm. 2008-06-17

#### **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.