

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078907218

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078540831



## Material Safety Data Sheet

Date Prepared: 10/10/03  
Prepared By: RC Park  
Technical Assistance: 607-562-2700

X-GEN Pharmaceuticals  
PO Box 445  
Big Flats, NY 14814

**AMPHOTERICIN B**

### IDENTIFICATION

**Common Name:** Amphotericin B

**Chemical Name:** Amphotericin B

**Synonym:** Amphotericin

**Formula:**  $C_{47}H_{73}NO_{17}$

**CAS Number:** 1397-89-3

**RTECS Number:** BU2625000

**Chemical Family:** A Macrolide antibiotic

**Therapeutic Category:** Antifungal

### INGREDIENT INFORMATION

Principle Components  
Amphotericin B

Percent  
Pure Material

Exposure Limits  
n/f

### HEALTH HAZARD INFORMATION

**Usual Adult Dose:** Amphotericin B is usually administered as 1 mg (base) initially, gradually increased to a maximum of 50 mg per day by intravenous infusion. The oral adult dose of Amphotericin B is 10 to 200 mg given four times a day as a lozenge or in tablet form. Amphotericin B is also applied topically to the skin, as a 3% cream, two to four times a day.

**Adverse Effects:** Adverse effects following ingestion may include nausea, vomiting, and diarrhea; adverse effects following topical application may include burning, itching, redness or other signs of irritation. Systemic effects following injection include unusual tiredness; irregular heartbeat; muscle cramps or pain; change in urination; blurred or double vision; itching; trouble breathing; wheezing; tightness in chest; sore throat; fever; shaking chills; numbness, tingling, pain, or weakness in hands or feet; seizures; unusual bleeding or bruising; indigestion; loss of appetite; stomach pain; leg, back, or neck pain; headache; and dizziness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** n/f

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization and kidney failure. Prolonged contact with skin may cause contact dermatitis and defatting.

**Inhalation:** May cause irritation. Remove to fresh air.

**n/f = not found**

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## AMPHOTERICIN B

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### HEALTH HAZARD INFO CONTINUED

**Eye:** May cause irritation. Flush with copious quantities of water.

**Skin:** May cause irritation. Flush with copious quantities of water.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is not absorbed from the gastrointestinal tract.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material and impaired kidney function.

**Cross Sensitivity:** n/f

**Pregnancy Comments:** Adequate and well-controlled pregnancy studies in humans have not been done. However, no adverse fetal effects have been documented in numerous case reports where Amphotericin B was used in all stages of pregnancy. Some studies in animals have not shown that Amphotericin B causes adverse effects on the fetus; however, some studies involving rabbits at twice the recommended human dose revealed a higher rate of miscarriage.

**Pregnancy Category:** B

### FIRST AID MEASURES

**General:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

**Overdose Treatment:** Treatment is generally supportive and symptomatic. Amphotericin B is not removed by hemodialysis. The patient's clinical status, including cardio-respiratory and hematologic status, liver and kidney function, and serum electrolytes should be monitored. [USP DI 20th ed. 2000]

### TOXICOLOGICAL INFORMATION

**Oral Rat:** LD50: >5 grams/kg

**Oral Mouse:** LD50: >8 grams/kg

**Irritancy Data:** n/f

**Target Organ(s):** Kidneys

**Listed as a Carcinogen?** NTP: No IARC: No OSHA: No Other: No

### FIREFIGHTING MEASURES

**Flash Point:** n/f

**Upper Flammable Limit:** n/f

**Auto-Ignition Temperature:** n/f

**Lower Flammable Limit:** n/f

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**n/f = not found**

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**AMPHOTERICIN B**

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**FIREFIGHTING MEASURES CONTINUED**

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**PHYSICAL HAZARDS**

**Conditions to Avoid:** Avoid exposure to light, heat, and moisture.

**Incompatibilities:** Sodium hydroxide.

**Decomposition Products:** When heated to decomposition material emits toxic fumes of NO<sub>x</sub>. Emits toxic fumes under fire conditions.

**Stable?** Yes

**Hazardous Polymerization?** No

**HANDLING / SPILL / DISPOSAL MEASURES**

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a cold place.

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

**Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

**EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Respiratory Protection:** When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

**Ventilation:** No special ventilation requirements.

**Gloves:** Rubber

**Eye Protection:** Safety Glasses

**Protective Clothing:** Protect exposed skin.

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**AMPHOTERICIN B**

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<b>PHYSICAL AND CHEMICAL PROPERTIES</b>
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**NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!**

**Appearance and Odor:** Yellow to orange powder; odorless or practically so.

**Melting Point:** > 170° C (decomposes gradually)

**Solubility in Water:** Insoluble

**Vapor Density:** n/f

**Solubility in Water:** Insoluble

**Evaporation Rate:** n/f

**Boiling Point:** n/f

**Evaporation Rate:** n/f

**Specific Gravity:** n/f

**Reactivity in Water:** n/f

**Vapor Pressure:** n/f

**% Volatile by Volume:** n/f



Safety Data Sheet

# Amphotericin B for Injection, USP

## Section 1: Chemical Product and Company Identification

**Product Name:** Amphotericin B for Injection, USP

**Chemical Name(s):** Amphotericin B

**Synonym:** Not available

**CAS Number:** 1397-89-3

**RTECS #:** BU2625000

**Trade Name:** Not available

**Chemical Formula:**  $C_{47}H_{73}NO_{17}$



Health	2
Fire	1
Reactivity	0
Personal Protection	E

**Contact Information:**

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

**Technical Assistance:** 607-562-2700

**Online Assistance:** [www.x-gen.us](http://www.x-gen.us)

**Emergency phone number:**

National Poison Control

1-800-222-1222

\*\*For information regarding recommended uses and restrictions on usage refer to the product package insert.

## Section 2: Hazard Identification

**Hazard pictograms (GHS-US):**



**Potential Acute Health Effects:** Hazardous in case of skin contact (irritant), or inhalation.

**Potential Chronic Health Effects:** Hazardous in case of skin contact (irritant), or inhalation.

**Carcinogenic Effects:** Not available

**Mutagenic Effects:** Not available

**Teratogenic Effects:** Some studies in animals have not shown that Amphotericin B causes adverse effects on the fetus; however, some studies involving rabbits at twice the recommended human dose revealed a higher rate of miscarriage.

**Developmental Toxicity:** The substance is toxic to blood, cardiovascular system, upper respiratory tract. Repeated or prolonged exposure to the substance can produce target organ damage.

**Adverse effects:** Adverse effects following ingestion may include nausea, vomiting, diarrhea; adverse effects following topical application may include burning, itching, redness or other signs of irritation. Systemic effects following injection include unusual tiredness, irregular heartbeat, muscle cramps or pain, change in urination, blurred or double vision, itching, trouble breathing, wheezing, tightness in chest, sore throat, fever, shaking from chills, numbness, tingling, pain or weakness in hands or feet, seizures, unusual bleeding or bruising, indigestion, loss of appetite, stomach pain, leg, back, or neck pain, headache, and dizziness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

### Section 3: Composition and Information on Ingredients

#### Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Amphotericin B	1397-89-3	100

### Section 4: First Aid Measures

**General:** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

**Skin contact:** In case of contact, immediately wash skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

**Eye contact:** Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

**Ingestion:** DO NOT induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call physician immediately. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

**Notes to physician:** Seek product package insert for complete information.

**Overdose Treatment:** Amphotericin B overdoses can result in potentially fatal cardiac or cardiopulmonary arrest. If an overdose is suspected, discontinue therapy and monitor the patient's

clinical status (e.g., cardiorespiratory, renal, and liver function, hematologic status, serum electrolytes) and administer supportive therapy, as required. Amphotericin B is not hemodialyzable. Prior to reinstituting therapy, the patient's condition should be stabilized (including correction of electrolyte deficiencies, etc.)

## **Section 5: Fire Fighting Measures**

**Flammability of the product:** May combust at high temperatures.

**Combustion Products:** These products are carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO<sub>2</sub>, NO<sub>3</sub>).

**Unusual Fire and Explosion Hazards:** This product is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

### **Extinguishing Media and Instruction:**

**Small fire:** Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. DO NOT use water jet.

**Protective equipment & precautions for firefighters:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

**Special remarks on fire hazard:** Not available

**Special remarks on explosion hazard:** Not available

## **Section 6: Accidental Release Measures**

### **Release to land:**

**Small spill:** Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

**Large spill:** Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

**Release to air:** If dust is generated, wear a disposable dust respirator (N95), and reduce exposures by ventilating area.

**Release to Water:** Refer to local water authority; drain disposal is not recommended.



**Protective equipment:** Keep unnecessary personnel away. Wear approved respiratory protection, chemically compatible gloves and protective clothing such as protective coveralls and shoe covers for spills.

## Section 7: Handling and Storage

**Handling:** As a general rule, when handling Amphotericin B for Injection, USP, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. DO NOT breathe dust. Avoid contact with skin. Wear suitable protective clothing. If you feel unwell, seek medical attention and show label when possible.

**Storage:** Keep container tightly closed. Store container in a refrigerated conditions, 2° - 8°C (36° - 46°F) (see USP CRT storage conditions). Refer to label instructions to ensure product integrity.

**Incompatibilities:** Keep away from Sodium Hydroxide.

## Section 8: Exposure Controls / Personal Protection

**Engineering controls:** No special ventilation requirements. May use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Personal protection:** Safety glasses, lab coat, gloves, and dust respirator. Be sure to use an approved/certified respirator or equivalent. **In case of large spill:** Splash goggles, full suit, dust respirator, boots and gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

**Respiratory protection:** Under normal use, respirators are not required. If dusts are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Exposure limit:** Not available

## Section 9: Physical and Chemical Properties

**Physical appearance:** Solid powder

**Color:** Dark yellow

**Molecular Weight:** 924.08

**Taste:** Not available

**Odor:** Odorless

**Odor Threshold:** Not available

**pH:** Not available

**Melting Point:** 170 °C (338°F)

**Freezing Point:** Not available  
**Boiling Point:** Not available  
**Flash Point:** Not available  
**Evaporation rate:** Not available  
**Flammability:** Not available  
**Upper Flammable Limit:** Not available  
**Lower Flammable Limit:** Not available  
**Vapor Pressure:** Not available  
**Vapor Density:** Not available

**Relative density:** Not available  
**Partition Coefficient:** Not available  
**Auto-Ignition Temperature:** Not available  
**Decomposition Temperature:** Not available  
**Viscosity:** Not available  
**Dispersion Properties:** Not available  
**Solubility:** Partially soluble in methanol.  
Insoluble in cold water.

## Section 10: Stability and Reactivity

**Reactivity:** Stable

**Chemical stability:** Stable

**Possibility of hazardous reaction:** Not available

**Conditions to avoid:** Avoid exposure to light, heat, and moisture.

**Incompatible materials:** Reactive with acids and oxidizing agents.

**Hazardous decomposition products:** When heated to decomposition material emits toxic fumes of NO<sub>x</sub>. Emits toxic fumes under fire conditions.

**Corrosivity:** Non-corrosive in presence of glass.

**Polymerization:** Will not occur.

## Section 11: Toxicological Information

**Routes of exposure:** Absorbed through skin, eye contact, inhalation and ingestion.

### Symptoms:

**Short term:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation. **Long term:** Hazardous in cases of skin contact and inhalation. Possible hyper sensitization and kidney failure. Prolonged contact with skin may cause contact dermatitis and defatting. May cause damage to the following organs: blood, cardiovascular system, upper respiratory tract, kidneys.

**Reproductive toxicity:** Adequate and well-controlled pregnancy studies in humans have not been done. However, no adverse fetal effects have been documented in numerous case reports where Amphotericin B was used in all stages of pregnancy. Some studies in animals have not shown that Amphotericin B causes adverse effects on the fetus; however, some studies involving rabbits at twice the recommended human dose revealed a higher rate of miscarriage.

**FDA Pregnancy Category:** B

**Toxicity to animals:**

**Oral Rat:** LD50: >5 grams/kg

**Oral Mouse:** LD50: >8 grams/kg

**Measures of toxicity:** Not available

**Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).**

#### **Section 12: Ecological Information**

**Ecotoxicity:** Not available

**Bioaccumulation potential:** Not available

**Products of biodegradation:** Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

**Toxicity of the products of biodegradation:** The products of degradation are more toxic.

#### **Section 13: Disposal Information**

**Waste classification:** Not available

**Waste from residues/unused products:** Dispose of waste in accordance with all applicable federal, state and local laws.

**Waste Disposal:** Dispose of waste in accordance with all applicable federal, state and local laws.

#### **Section 14: Transport Information**

**DOT Classification:** Not a DOT controlled material (United States).

**UN Number:** Not available

**UN Shipping name:** Not available

**Transport hazard class:** Not available

**Packing Group:** Not available

**Environmental hazard:** Not available

**Transport in bulk:** Not available

**Special precautions needed with transport:** Not available

#### **Section 15: Regulatory Information**

**Federal and State Regulations:** Not available

**Other Regulations:** OSHA: Hazardous by definition of Hazardous Communication Standards (29 CFR 1910.1200).

**Other Classifications:**

**WHMIS (Canada):** Not controlled under WHMIS (Canada).

**DSCL (EEC):** R38 - Irritating to skin. S2 – Keep out of the reach of children. S46 – If swallowed, seek medical advice immediately and show the container or label.

**HMIS (U.S.A.):**

**Health Hazard:** 2

**Fire Hazard:** 1

**Reactivity:** 0

**Personal Protection:** E

**National Fire Protection Association (U.S.A.):**

**Health:** 2

**Flammability:** 1

**Reactivity:** 0

**Protective Equipment:** Gloves, lab coat, safety glasses, and dust respirator. Be sure to use an approved/certified respirator or equivalent.

**Section 16: Other Information**

**References:** Not available

**Created:** 1/30/2015

**Last Updated:** 3/27/2015

**Prepared & Approved by:** X-GEN Pharmaceuticals, Inc., Safety Committee

*The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.*



Safety Data Sheet

# Amphotericin B for Injection, USP

## Section 1: Chemical Product and Company Identification

**Product Name:** Amphotericin B for Injection, USP

**Chemical Name(s):** Amphotericin B

**Synonym:** Not available

**CAS Number:** 1397-89-3

**RTECS #:** BU2625000

**Trade Name:** Not available

**Chemical Formula:**  $C_{47}H_{73}NO_{17}$



Health	2
Fire	1
Reactivity	0
Personal Protection	E

**Contact Information:**

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

**Technical Assistance:** 607-562-2700

**Online Assistance:** [www.x-gen.us](http://www.x-gen.us)

**Emergency phone number:**

National Poison Control

1-800-222-1222

\*\*For information regarding recommended uses and restrictions on usage refer to the product package insert.

## Section 2: Hazard Identification

**Hazard pictograms (GHS-US):**



**Potential Acute Health Effects:** Hazardous in case of skin contact (irritant), or inhalation.

**Potential Chronic Health Effects:** Hazardous in case of skin contact (irritant), or inhalation.

**Carcinogenic Effects:** Not available

**Mutagenic Effects:** Not available

**Teratogenic Effects:** Some studies in animals have not shown that Amphotericin B causes adverse effects on the fetus; however, some studies involving rabbits at twice the recommended human dose revealed a higher rate of miscarriage.

**Developmental Toxicity:** The substance is toxic to blood, cardiovascular system, upper respiratory tract. Repeated or prolonged exposure to the substance can produce target organ damage.

**Adverse effects:** Adverse effects following ingestion may include nausea, vomiting, diarrhea; adverse effects following topical application may include burning, itching, redness or other signs of irritation. Systemic effects following injection include unusual tiredness, irregular heartbeat, muscle cramps or pain, change in urination, blurred or double vision, itching, trouble breathing, wheezing, tightness in chest, sore throat, fever, shaking from chills, numbness, tingling, pain or weakness in hands or feet, seizures, unusual bleeding or bruising, indigestion, loss of appetite, stomach pain, leg, back, or neck pain, headache, and dizziness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

### Section 3: Composition and Information on Ingredients

#### Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Amphotericin B	1397-89-3	100

### Section 4: First Aid Measures

**General:** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

**Skin contact:** In case of contact, immediately wash skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

**Eye contact:** Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

**Ingestion:** DO NOT induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call physician immediately. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

**Notes to physician:** Seek product package insert for complete information.

**Overdose Treatment:** Amphotericin B overdoses can result in potentially fatal cardiac or cardiopulmonary arrest. If an overdose is suspected, discontinue therapy and monitor the patient's

clinical status (e.g., cardiorespiratory, renal, and liver function, hematologic status, serum electrolytes) and administer supportive therapy, as required. Amphotericin B is not hemodialyzable. Prior to reinstituting therapy, the patient's condition should be stabilized (including correction of electrolyte deficiencies, etc.)

## **Section 5: Fire Fighting Measures**

**Flammability of the product:** May combust at high temperatures.

**Combustion Products:** These products are carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO<sub>2</sub>, NO<sub>3</sub>).

**Unusual Fire and Explosion Hazards:** This product is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

### **Extinguishing Media and Instruction:**

**Small fire:** Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. DO NOT use water jet.

**Protective equipment & precautions for firefighters:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

**Special remarks on fire hazard:** Not available

**Special remarks on explosion hazard:** Not available

## **Section 6: Accidental Release Measures**

### **Release to land:**

**Small spill:** Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

**Large spill:** Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

**Release to air:** If dust is generated, wear a disposable dust respirator (N95), and reduce exposures by ventilating area.

**Release to Water:** Refer to local water authority; drain disposal is not recommended.

**Protective equipment:** Keep unnecessary personnel away. Wear approved respiratory protection, chemically compatible gloves and protective clothing such as protective coveralls and shoe covers for spills.

## Section 7: Handling and Storage

**Handling:** As a general rule, when handling Amphotericin B for Injection, USP, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. DO NOT breathe dust. Avoid contact with skin. Wear suitable protective clothing. If you feel unwell, seek medical attention and show label when possible.

**Storage:** Keep container tightly closed. Store container in a refrigerated conditions, 2° - 8°C (36° - 46°F) (see USP CRT storage conditions). Refer to label instructions to ensure product integrity.

**Incompatibilities:** Keep away from Sodium Hydroxide.

## Section 8: Exposure Controls / Personal Protection

**Engineering controls:** No special ventilation requirements. May use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Personal protection:** Safety glasses, lab coat, gloves, and dust respirator. Be sure to use an approved/certified respirator or equivalent. **In case of large spill:** Splash goggles, full suit, dust respirator, boots and gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

**Respiratory protection:** Under normal use, respirators are not required. If dusts are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Exposure limit:** Not available

## Section 9: Physical and Chemical Properties

**Physical appearance:** Solid powder

**Color:** Dark yellow

**Molecular Weight:** 924.08

**Taste:** Not available

**Odor:** Odorless

**Odor Threshold:** Not available

**pH:** Not available

**Melting Point:** 170 °C (338°F)



**Freezing Point:** Not available  
**Boiling Point:** Not available  
**Flash Point:** Not available  
**Evaporation rate:** Not available  
**Flammability:** Not available  
**Upper Flammable Limit:** Not available  
**Lower Flammable Limit:** Not available  
**Vapor Pressure:** Not available  
**Vapor Density:** Not available

**Relative density:** Not available  
**Partition Coefficient:** Not available  
**Auto-Ignition Temperature:** Not available  
**Decomposition Temperature:** Not available  
**Viscosity:** Not available  
**Dispersion Properties:** Not available  
**Solubility:** Partially soluble in methanol.  
Insoluble in cold water.

## Section 10: Stability and Reactivity

**Reactivity:** Stable

**Chemical stability:** Stable

**Possibility of hazardous reaction:** Not available

**Conditions to avoid:** Avoid exposure to light, heat, and moisture.

**Incompatible materials:** Reactive with acids and oxidizing agents.

**Hazardous decomposition products:** When heated to decomposition material emits toxic fumes of NO<sub>x</sub>. Emits toxic fumes under fire conditions.

**Corrosivity:** Non-corrosive in presence of glass.

**Polymerization:** Will not occur.

## Section 11: Toxicological Information

**Routes of exposure:** Absorbed through skin, eye contact, inhalation and ingestion.

### Symptoms:

**Short term:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation. **Long term:** Hazardous in cases of skin contact and inhalation. Possible hyper sensitization and kidney failure. Prolonged contact with skin may cause contact dermatitis and defatting. May cause damage to the following organs: blood, cardiovascular system, upper respiratory tract, kidneys.

**Reproductive toxicity:** Adequate and well-controlled pregnancy studies in humans have not been done. However, no adverse fetal effects have been documented in numerous case reports where Amphotericin B was used in all stages of pregnancy. Some studies in animals have not shown that Amphotericin B causes adverse effects on the fetus; however, some studies involving rabbits at twice the recommended human dose revealed a higher rate of miscarriage.

**FDA Pregnancy Category:** B

**Toxicity to animals:**

**Oral Rat:** LD50: >5 grams/kg

**Oral Mouse:** LD50: >8 grams/kg

**Measures of toxicity:** Not available

**Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).**

### **Section 12: Ecological Information**

**Ecotoxicity:** Not available

**Bioaccumulation potential:** Not available

**Products of biodegradation:** Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

**Toxicity of the products of biodegradation:** The products of degradation are more toxic.

### **Section 13: Disposal Information**

**Waste classification:** Not available

**Waste from residues/unused products:** Dispose of waste in accordance with all applicable federal, state and local laws.

**Waste Disposal:** Dispose of waste in accordance with all applicable federal, state and local laws.

### **Section 14: Transport Information**

**DOT Classification:** Not a DOT controlled material (United States).

**UN Number:** Not available

**UN Shipping name:** Not available

**Transport hazard class:** Not available

**Packing Group:** Not available

**Environmental hazard:** Not available

**Transport in bulk:** Not available

**Special precautions needed with transport:** Not available

### **Section 15: Regulatory Information**

**Federal and State Regulations:** Not available

**Other Regulations:** OSHA: Hazardous by definition of Hazardous Communication Standards (29 CFR 1910.1200).

**Other Classifications:**

**WHMIS (Canada):** Not controlled under WHMIS (Canada).

**DSCL (EEC):** R38 - Irritating to skin. S2 – Keep out of the reach of children. S46 – If swallowed, seek medical advice immediately and show the container or label.

**HMIS (U.S.A.):**

**Health Hazard:** 2

**Fire Hazard:** 1

**Reactivity:** 0

**Personal Protection:** E

**National Fire Protection Association (U.S.A.):**

**Health:** 2

**Flammability:** 1

**Reactivity:** 0

**Protective Equipment:** Gloves, lab coat, safety glasses, and dust respirator. Be sure to use an approved/certified respirator or equivalent.

**Section 16: Other Information**

**References:** Not available

**Created:** 1/30/2015

**Last Updated:** 3/27/2015

**Prepared & Approved by:** X-GEN Pharmaceuticals, Inc., Safety Committee

*The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.*