



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

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 reinstating 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, CO₂), nitrogen oxides (NO₂, NO₃).

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_x. 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.