



Material Safety Data Sheet

Date Prepared: 10/10/03

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X-GEN Pharmaceuticals

PO Box 445

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AMPHOTERICIN B

IDENTIFICATION

Common Name: Amphotericin B

Chemical Name: Amphotericin B

Synonym: Amphotericin

Formula: C₄₇H₇₃NO₁₇

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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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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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 NOx. 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.

n/f = not found

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PHYSICAL AND CHEMICAL PROPERTIES

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

n/f = not found