1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Amphotericin B Injection

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>AMPHOVIN(R) INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as antibiotic agent</td>
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</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Yellow to orange lyophilised cake

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
- **Short Term:** Acute toxicity following ingestion is not expected. May cause allergic reactions in susceptible individuals.
- **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, reproductive system.

Known Clinical Effects: May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Serious allergic reactions, including anaphylaxis, have been reported. Kidney dysfunction has been seen during clinical use.

EU Indication of danger: Not classified


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

AMPHOTERICIN B INJECTION
Hazardous Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | %
--- | --- | --- | --- | ---
Amphotericin B | 1397-89-3 | 215-742-2 | Not Listed | 45

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
7. HANDLING AND STORAGE

General Handling: Use appropriate personal protective equipment. Avoid inhalation and contact with skin, eye, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
- Hands: Wear impervious gloves if skin contact is possible.
- Eyes: Safety glasses or goggles
- Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
- Respiratory protection: Respiratory protection is not expected to be necessary under normal handling conditions; required only if dust is generated.

9. PHYSICAL AND CHEMICAL PROPERTIES:

- Physical State: Lyophilized powder
- Odor: None
- Molecular Weight: Mixture
- Solubility: Slightly Soluble: Water
- Color: Yellow/orange
- Molecular Formula: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: None known
Hazardous Decomposition Products: None known

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Amphotericin B
- Rat Oral LD50 > 5000 mg/kg
- Rat Intravenous LD50 1.6 mg/kg
- Rat Intraperitoneal LD50 > 5000 mg/kg
- Mouse Intravenous LD50 1.2 mg/kg
Acute Toxicity Comments: A greater than symbol (>\) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium phosphate, dibasic
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Amphotericin B
30 Day(s)  Dog  Intravenous  37 mg/kg/day  LOAEL  Kidney
2 Month(s)  Dog  Intravenous  16.5 mg/kg/day  LOAEL  Kidney
13 Week(s)  Rat  Oral  2 mg/kg/day  NOAEL  Male reproductive system, Female reproductive system
13 Week(s)  Dog  Oral  1.6 mg/kg/day  NOAEL  Male reproductive system, Female reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Amphotericin B
Embryo / Fetal Development  Rat  Oral  7.5 mg/kg/day  NOAEL  Not teratogenic, Fetotoxicity
Embryo / Fetal Development  Rabbit  Oral  10 mg/kg/day  NOAEL  Not Teratogenic, Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Amphotericin B
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vivo Micronucleus  Mouse  Negative
In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Deoxycholic acid, sodium salt
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 206-132-7

Sodium phosphate, dibasic
   CERCLA/SARA Hazardous Substances = 2270 kg final RQ
   and their Reportable Quantities: = 5000 lb final RQ
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 231-448-7

Sodium phosphate, monobasic
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 231-449-2

Amphotericin B
   Australia (AICS): Present
   Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
   EU EINECS/ELINCS List 215-742-2

16. OTHER INFORMATION

Data Sources:
Safety data sheets for individual ingredients. Publicly available toxicity information. Pfizer proprietary drug development information.
Revised: 20-Dec-2007

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet