SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: AmBisome® (Amphotericin B) Liposome for Injection

Material Name: Amphotericin B

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


1.2. Intended Use of the Product

Use of the substance/mixture: Anti-fungal antibiotic.

1.3. Name, Address, and Telephone of the Responsible Party

Company
Astellas US LLC
1 Astellas Way
Northbrook, IL 60062
Tel.: 800-888-7704
www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003 Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Comb. Dust

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : May form combustible dust concentrations in air.

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Accidental exposure or overdose may cause anemia, hypokalemia, infusion related reaction, renal function impairment, thrombophlebitis, blurred or double vision, cardiac arrhythmias, hypersensitivity, leucopenia, polyneuropathy, seizures, thrombocytopenia, myelosuppression, GI disturbance and headache, angioedema, erythema, urticaria, bronchospasm, cyanosis/hypoxia, pulmonary edema, agranulocytosis, hemorrhagic cystitis, rhabdomyolysis, and anaphylaxis.

2.4. Unknown Acute Toxicity (GHS-US)

< 5 percent of the mixture consists of ingredient(s) of unknown acute toxicity.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>(CAS No) 57-50-1</td>
<td>&lt; 70</td>
<td>Comb. Dust</td>
</tr>
<tr>
<td>Soybean lecithin</td>
<td>(CAS No) 8002-43-5</td>
<td>&lt; 20</td>
<td>Not classified</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>(CAS No) 57-88-5</td>
<td>&lt; 5</td>
<td>Not classified</td>
</tr>
<tr>
<td>Butanedioic acid, disodium salt</td>
<td>(CAS No) 150-90-3</td>
<td>&lt; 5</td>
<td>Not classified</td>
</tr>
<tr>
<td>Succinate, disodium, hexahydrate</td>
<td>(CAS No) 6106-21-4</td>
<td>&lt; 5</td>
<td>Skin Irrit. 2, H315, Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td>Amphotericin B</td>
<td>(CAS No) 1397-89-3</td>
<td>&lt; 5</td>
<td>Skin Irrit. 2, H315, Eye Irrit. 2A, H319, STOT SE 3, H335</td>
</tr>
<tr>
<td>Distearoyl phophatidylglycerol</td>
<td>(CAS No) 4537-78-4</td>
<td>&lt; 5</td>
<td>Not classified</td>
</tr>
</tbody>
</table>
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| 2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecy1)-, [2R-[2R*(4R*,8R*)]]- | (CAS No) 59-02-9 | < 1 | Not classified |

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures
First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).
First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
First-aid Measures After Skin Contact: Rinse immediately with plenty of water. Obtain medical attention if irritation develops or persists.
First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed
If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media
Suitable Extinguishing Media: Water spray, fog, alcohol-resistant foam, carbon dioxide (CO₂), dry chemical powder.
Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture
Fire Hazard: May form combustible dust concentrations in air.
Explosion Hazard: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters
Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures
General Measures: Avoid all contact with skin, eyes, or clothing. Avoid breathing (dust). Avoid generating dust.

6.1.1. For Non-emergency Personnel
Protective Equipment: Use appropriate personal protection equipment (PPE).

6.1.2. For Emergency Responders
Protective Equipment: Equip cleanup crew with proper protection.

6.2. Environmental Precautions
Prevent entry to sewers and public waters.
6.3. Methods and Material for Containment and Cleaning Up
For Containment: Contain and collect as any solid.
Methods for Cleaning Up: Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Use only non-sparking tools. Clear up spills immediately and dispose of waste safely. Contact competent authorities after a spill.

6.4. Reference to Other Sections
See Heading 8. Exposure controls and personal protection. Concerning disposal elimination after cleaning, see item 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling
Additional Hazards When Processed: Good housekeeping is needed during storage, transfer, handling, and use of this material to avoid excessive dust accumulation. Proper grounding procedures to avoid static electricity should be followed. Use only non-sparking tools.
Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities
Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.
Storage Temperature: < 25 °C (< 77 °F)

7.3. Specific End Use(s)
Anti-fungal antibiotic.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters
For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

<table>
<thead>
<tr>
<th>Sugarcane (57-50-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>USA ACGIH</strong> ACGIH TWA (mg/m³)</td>
</tr>
<tr>
<td><strong>USA NIOSH</strong> NIOSH REL (TWA) (mg/m³)</td>
</tr>
<tr>
<td><strong>USA OSHA</strong> OSHA PEL (TWA) (mg/m³)</td>
</tr>
</tbody>
</table>

8.2. Exposure Controls
Appropriate Engineering Controls: Prevent dust accumulation (to minimize explosion hazard). It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.


Materials for Protective Clothing: Chemically resistant materials and fabrics.
Hand Protection: Wear chemically resistant protective gloves.
Eye Protection: Chemical goggles or safety glasses.
Skin and Body Protection: Wear suitable protective clothing.
Respiratory Protection: Use NIOSH-approved dust mask if dust has the potential to become airborne.
Environmental Exposure Controls: Do not allow the product to be released into the environment.
Consumer Exposure Controls: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties
Physical State: Solid
### Appearance
Yellow/Orange Lyophilized product

### Odor
None

### Odor Threshold
No data available

### pH
5 - 6 (reconstituted solution)

### Evaporation Rate
No data available

### Melting Point
> 170 °C (338°F) (dec)

### Freezing Point
No data available

### Boiling Point
No data available

### Flash Point
No data available

### Auto-ignition Temperature
No data available

### Decomposition Temperature
No data available

### Flammability (solid, gas)
No data available

### Vapor Pressure
No data available

### Relative Vapor Density at 20 °C
No data available

### Relative Density
No data available

### Solubility
Insoluble

### Partition Coefficient: N-Octanol/Water
No data available

### Viscosity
No data available

### Molecular Weight
924.09 (Amphotericin B)

### Other Information
No additional information available.

## SECTION 10: STABILITY AND REACTIVITY

### Reactivity
Hazardous reactions will not occur under normal conditions.

### Chemical Stability
Stable under recommended handling and storage conditions (see section 7).

### Possibility of Hazardous Reactions
Hazardous polymerization will not occur.

### Conditions to Avoid
Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.

### Incompatible Materials
Strong acids, strong bases, strong oxidizers.

### Hazardous Decomposition Products
Thermal decomposition generates: Carbon oxides (CO, CO₂).

## SECTION 11: TOXICOLOGICAL INFORMATION

### Information On Toxicological Effects

#### Acute Toxicity
Not classified

#### LD50 (Oral)
29,700.00 mg/kg

#### Skin Corrosion/Irritation
Not classified (pH: 5 - 6 [reconstituted solution])

#### Serious Eye Damage/Irritation
Not classified (pH: 5 - 6 [reconstituted solution])

#### Respiratory or Skin Sensitization
Not classified

#### Germ Cell Mutagenicity
Not classified (AmBisome has not been tested to determine its mutagenic potential.)

#### Carcinogenicity
Not classified (No long term studies in animals have been performed to evaluate carcinogenic potential of AmBisome.)

### Cholesterol (57-88-5)

<table>
<thead>
<tr>
<th>IARC group</th>
<th>3</th>
</tr>
</thead>
</table>

#### Reproductive Toxicity
Not classified (A Segment I Reproductive Study in rats found an abnormal estrous cycle [prolonged diestrus] and decreased number of corpora lutea in the high dose groups [10 and 15 mg/kg, doses equivalent to human doses of 1.6 and 2.4 mg/kg based on body surface area considerations]. AmBisome did not affect fertility or days to copulation. There were no effects on male reproductive function. Rabbits receiving doses equivalent to 0.5 to 2 times the recommended human dose experienced a higher rate of spontaneous abortions than control animals.)

#### Specific Target Organ Toxicity (Single Exposure)
Not classified

#### Specific Target Organ Toxicity (Repeated Exposure)
Not classified

#### Aspiration Hazard
Not classified

#### Symptoms/Injuries After Inhalation
Prolonged inhalation of dust may cause respiratory irritation.

#### Symptoms/Injuries After Skin Contact
Dust may cause irritation in skin folds or by contact in combination with tight clothing.

#### Symptoms/Injuries After Eye Contact
Prolonged contact with large amounts of dust may cause mechanical irritation.
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Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.
Symptoms/Injuries After Accidental Injection: Accidental exposure or overdose may cause anemia, hypokalemia, infusion related reaction, renal function impairment, thrombophlebitis, blurred or double vision, cardiac arrhythmias, hypersensitivity, leucopenia, polynuropathy, seizures, thrombocytopenia, myelosuppression, GI disturbance and headache, angioedema, erythema, urticaria, bronchospasm, cyanosis/hypoventilation, pulmonary edema, agranulocytosis, hemorrhagic cystitis, and rhabdomyolysis.
Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION
12.1. Toxicity No additional information available.
12.2. Persistence and Degradability No additional information available.
12.3. Bioaccumulative Potential No additional information available.
12.4. Mobility in Soil No additional information available.
12.5. Other Adverse Effects
Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS
13.1. Waste treatment methods
Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION
14.1. In Accordance with DOT Not regulated for transport.
14.2. In Accordance with IMDG Not regulated for transport.
14.3. In Accordance with IATA Not regulated for transport.

SECTION 15: REGULATORY INFORMATION
15.1 US Federal Regulations
Soybean lecithin (8002-43-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Cholesterol (57-88-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-, [2R-[2R*(4R*,8R*)]]- (59-02-9)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Sucrose (57-50-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Butanediolic acid, disodium salt (150-90-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations
Sucrose (57-50-1)
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION
Revision Date : 01/22/2015
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

<table>
<thead>
<tr>
<th>Comb. Dust</th>
<th>Combustible Dust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
</tbody>
</table>

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)