

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

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

Material Name: Amphotericin B

Formula: C₄₇H₇₃NO₁₇

Chemical Name of Active Ingredient: [1R-(1R*,3S*,5R*,6R*,9R*,11R*,15S*,16R*,17R*,18S*,19E,21E,23E,25E,27E,29E,31E,33R*,35S*,36R*,37S*)]-33-[(3-Amino-3,6-dideoxy-β-D-mannopyranosyl)oxy]-1,3,5,6,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,23,25,27,29,31-heptaene-36-carboxylic acid

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/hypoventilation, 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

Name	Product Identifier	%	Classification (GHS-US)
Sucrose	(CAS No) 57-50-1	< 70	Comb. Dust
Soybean lecithin	(CAS No) 8002-43-5	< 20	Not classified
Cholesterol	(CAS No) 57-88-5	< 5	Not classified
Butanedioic acid, disodium salt	(CAS No) 150-90-3	< 5	Not classified
Succinate, disodium, hexahydrate	(CAS No) 6106-21-4	< 5	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Amphotericin B	(CAS No) 1397-89-3	< 5	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Distearoyl phosphatidylglycerol	(CAS No) 4537-78-4	< 5	Not classified

AmBisome® (Amphotericin B) Liposome for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-, [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.

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.

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, polyneuropathy, 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.

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).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Stop leak if safe to do so. Eliminate ignition sources. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

AmBisome® (Amphotericin B) Liposome for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

Technical Measures: Ground/bond container and receiving equipment. Use explosion-proof electrical, ventilating, and lighting equipment. Comply with applicable regulations.

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.

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

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).

Sucrose (57-50-1)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)

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.

Personal Protective Equipment

: Protective goggles. Gloves. Protective clothing. Dust formation: dust mask.



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

AmBisome® (Amphotericin B) Liposome for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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)

9.2. Other Information No additional information available.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Sucrose (57-50-1)	
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)	
IARC group	3

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.

AmBisome® (Amphotericin B) Liposome for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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, polyneuropathy, 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.

Ecology – Waste Materials: Avoid release to the environment.

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

Butanedioic 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:

Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H319	Causes serious eye irritation

AmBisome® (Amphotericin B) Liposome for Injection

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

H335	May cause respiratory irritation
------	----------------------------------

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)