

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Mycamine® (Micafungin sodium) for Injection

Material Name: Micafungin sodium

CAS No: 208538-73-2

Chemical Name of Active Ingredient: Pneumocandin A0,1-[(4*R*,5*R*)-4,5-dihydroxy-*N*²-[4-[5-[4-(pentyloxy)phenyl]-3-isoxazolyl]benzoyl]-L-ornithine]-4-[(4*S*)-4-hydroxy-4-[4-hydroxy-3-(sulfooxy)phenyl]-L-threonine]-, monosodium salt

Chemical Formula of Active Ingredient: C₅₆H₇₀N₉NaO₂₃S

1.2. Intended Use of the Product

Use of the substance/mixture: Anti-fungal. For professional use only.

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

The toxicological, physical and other potential hazards associated with this compound have not been fully characterized. Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

< 40 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)
Lactose	(CAS No) 63-42-3	< 70	Comb. Dust
Micafungin sodium	(CAS No) 208538-73-2	< 40	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 if pain, blinking, or redness persist.

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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: None expected under normal conditions of use.

Symptoms/Injuries After Inhalation: Dust from this product may cause irritation to the respiratory tract.

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 may cause nausea, vomiting and diarrhea.

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, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

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: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Combustible dust. Fine dust clouds may form explosive mixtures with air.

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: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Take up large spills with pump or vacuum. Contact competent authorities after a spill. Avoid generation of dust during clean-up of spills.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Local exhaust is recommended where dust may occur.

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: Comply with applicable regulations. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof electrical, ventilating, and lighting equipment.

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 oxidizers.

Storage Temperature: 25 °C (77 °F), excursions permitted to 15 - 30°C (59 - 86 °F)

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7.3. Specific End Use(s)

Anti-fungal. For professional use only.

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).

8.2. Exposure Controls

Appropriate Engineering Controls

: 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. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment.

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

Appearance

: White lyophilized powder. Following reconstitution:

50 mg: single-use vials, coated with a light protective film and sealed with a blue flip-off cap.

100 mg: single-use vials, coated with a light protective film and sealed with a red flip-off cap.

Odor

: No data available

Odor Threshold

: No data available

pH

: 5 - 7 following reconstitution with 0.9% Sodium Chloride Injection

Evaporation Rate

: No data available

Melting Point

: No clean melting point

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

: In water: > 200 mg/mL

Partition Coefficient: N-Octanol/Water

: No data available

Viscosity

: No data available

Molecular Weight Of Active Ingredient

: 1292.26 g/mol

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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. Avoid creating or spreading dust.
- 10.5. Incompatible Materials:** Oxidizers.
- 10.6. Hazardous Decomposition Products:** Carbon oxides (CO, CO₂). Nitrogen oxides. sulfur oxides. Sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Micafungin Sodium (208538-73-2)	
Lethal Dose I.V. Rat	125 mg/kg (male)
Lethal Dose I.V. Rat	250 mg/kg (female)
Lethal Dose I.V. Dog	> 200 mg/kg

Lactose (63-42-3)	
LD50 Oral Rat	> 10 g/kg

Skin Corrosion/Irritation: Not classified **pH:** 5 - 7 following reconstitution with 0.9% Sodium Chloride Injection

Serious Eye Damage/Irritation: Not classified **pH:** 5 - 7 following reconstitution with 0.9% Sodium Chloride Injection

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Micafungin Sodium (208538-73-2)	
Additional information	Micafungin sodium was not mutagenic or clastogenic when evaluated in a standard battery of in-vitro and in-vivo tests (i.e., bacterial reversion - S. typhimurium, E. coli; chromosomal aberration; intravenous mouse micronucleus).

Carcinogenicity: Not classified

Micafungin Sodium (208538-73-2)	
Additional information	<p>Hepatic carcinomas and adenomas were observed in a 6-month intravenous toxicology study with an 18-month recovery period of micafungin sodium in rats designed to assess the reversibility of hepatocellular lesions.</p> <p>Rats administered micafungin sodium for 3 months at 32 mg/kg/day (corresponding to 8 times the highest recommended human dose [150 mg/day], based on AUC comparisons), exhibited colored patches/zones, multinucleated hepatocytes and altered hepatocellular foci after 1 or 3 month recovery periods, and adenomas were observed after a 21-month recovery period. Rats administered micafungin sodium at the same dose for 6 months exhibited adenomas after a 12-month recovery period; after an 18-month recovery period, an increased incidence of adenomas was observed, and additionally, carcinomas were detected. A lower dose of micafungin sodium (equivalent to 5 times the human AUC) in the 6-month rat study resulted in a lower incidence of adenomas and carcinomas following 18 months recovery. The duration of micafungin dosing in these rat studies (3 or 6 months) exceeds the usual duration of Mycamine dosing in patients, which is typically less than 1 month for treatment of esophageal candidiasis, but dosing may exceed 1 month for Candida prophylaxis.</p> <p>Although the increase in carcinomas in the 6-month rat study did not reach statistical significance, the persistence of altered hepatocellular foci subsequent to micafungin dosing, and the presence of adenomas and carcinomas in the recovery periods suggest a causal relationship between micafungin sodium, altered hepatocellular foci, and hepatic neoplasms. Whole-life carcinogenicity studies of Mycamine in animals have not been conducted,</p>

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	and it is not known whether the hepatic neoplasms observed in treated rats also occur in other species, or if there is a dose threshold for this effect.
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Reproductive Toxicity: Not classified

Micafungin Sodium (208538-73-2)

Additional information

Micafungin sodium administration to pregnant rabbits (intravenous dosing on days 6 to 18 of gestation) resulted in visceral abnormalities and abortion at 32 mg/kg, a dose equivalent to about four times the recommended dose based on body surface area comparisons. Visceral abnormalities included abnormal lobation of the lung, levocardia, retrocaval ureter, anomalous right subclavian artery, and dilatation of the ureter.

Male rats treated intravenously with micafungin sodium for 39 weeks showed vacuolation of the epididymal ductal epithelial cells at or above 10 mg/kg (about 0.6 times the recommended clinical dose for esophageal candidiasis, based on body surface area comparisons). Higher doses (about twice the recommended clinical dose, based on body surface area comparisons) resulted in higher epididymis weights and reduced numbers of sperm cells. In a 39-week intravenous study in dogs, seminiferous tubular atrophy and decreased sperm in the epididymis were observed at 10 and 32 mg/kg, doses equal to about 2 and 7 times the recommended clinical dose, based on body surface area comparisons. There was no impairment of fertility in animal studies with micafungin sodium.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Micafungin Sodium (208538-73-2)

Additional information

High doses of micafungin sodium (5 to 8 times the highest recommended human dose, based on AUC comparisons) have been associated with irreversible changes to the liver in rats when administered for 3 or 6 months, and these changes may be indicative of pre-malignant processes.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Dust from this product may cause irritation to the respiratory tract.

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 may cause nausea, vomiting and diarrhea.

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

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Lactose (63-42-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 06/10/2015

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

May form combustible dust concentrations in air

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.

Astellas US GHS SDS