

# MATERIAL SAFETY DATA SHEET



## MYCAMINE (MICA FUNGIN SODIUM) FOR INJECTION

Date Prepared:  
02/20/2003

Date Reviewed:  
02/20/2003

---

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Identifier: Micafungin  
General Use: Antifungal

#### MANUFACTURED FOR EMERGENCY TELEPHONE NUMBER

Astellas Pharma US, Inc. (800) 727-7003  
3 Parkway North  
Deerfield, IL 60015-2538  
(847) 317-8800

---

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Component:	<b>Citric Acid</b>			CAS Registry #:	77-92-9
				UN Number:	
OSHA PEL:	NE	mg/m3	OSHA PEL:	NE	ppm
ACGIH TLV:	NE	mg/m3	ACGIH TLV:	NE	ppm
STEL:	NE	mg/m3	STEL:	NE	ppm
Percent of Product:	NG		Note:	NG	

Component:	<b>Lactose</b>			CAS Registry #:	63-42-3
				UN Number:	NG
OSHA PEL:	NE	mg/m3	OSHA PEL:	NE	ppm

ACGIH TLV:	NE	mg/m3	ACGIH TLV:	NE	ppm
STEL:	NE	mg/m3	STEL:	NE	ppm

Percent of Product: NG Note: NG

Component: **Micafungin Sodium** CAS Registry #: 208538-73-2  
UN Number: NG

Chemical Name: (-) - Sodium 5-[1S, 2S) - 2 - [( 3S, 6S, 9S, 11R, 15S, 18S, 20R, 21R, 24S, 25S, 26S,) -18 -3- [(R) - 2 - carbamoyl- 1 - hydroxyethyl] - 11, 20, 21, 25 - tetrahydroxy - 15 - [(R)-1- hydroxyethyl] - 26-methyl- 2,5,8,14,17,23 - hexaoxo - 18- [4 -[5-(4-pentyloxyphenyl) isoxazol - 3 - yl] benzoylamino] -1,4,7,13,16,22, - hexaazatricyclo [ 22.3.0.0 9,13] heptacos-6-yl] - 1,2-dihydroxyethyl]-2-hydroxyphenyl sulfate

OSHA PEL:	NE	mg/m3	OSHA PEL:	NE	ppm
ACGIH TLV:	NE	mg/m3	ACGIH TLV:	NE	ppm
STEL:	NE	mg/m3	STEL:	NE	ppm

Percent of Product: NG Note: 50mg

Component: **Sodium Hydroxide** CAS Registry #: 1310-73-2  
UN Number: NG

OSHA PEL:	2	mg/m3	OSHA PEL:	NE	ppm
ACGIH TLV:	2	mg/m3	ACGIH TLV:	NE	ppm
STEL:	2	mg/m3	STEL:	NE	ppm

Percent of Product: NG Note: NG

### 3. HAZARD IDENTIFICATION

PRIMARY ROUTES OF EXPOSURE - Inhalation, Eye/Skin Absorption and Ingestion.

COMPONENT	CAS No.	NTP	IARC	OSHA	COMMENT
-----------	---------	-----	------	------	---------

Citric Acid	77-92-9	NO	NO	NO	NA
Lactose	63-42-3	No Data	No Data	No Data	NA
Micafungin Sodium	208538-73-2	No Data	No Data	No Data	
Sodium Hydroxide	1310-73-2	No Data	No Data	No Data	Sodium hydroxide is considered an eye irritant.

---

#### 4. EMERGENCY AND FIRST AID PROCEDURES

Inhalation: Move person to fresh air immediately. Give artificial respiration and Cardiopulmonary Resuscitation (CPR) if required. Seek medical attention.

Ingestion: Flush mouth out with water immediately. Seek medical attention.

Skin Contact: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

Eye Contact: Immediately flush with water for at least 15 minutes. If irritation persists, seek medical attention.

For Adverse Drug Reaction Information: phone: (847) 317-1276; fax: (847)-317-1241; email:safety@fujisawa.com

---

#### 5. FIRE FIGHTING MEASURES

Fire and Explosion Data:

Product Flammability:	Non-Flammable	Closed Cup Flash Pt.:	NA
Autoignition:	NA	Open Cup Flash Pt.:	NA
Flammability Limits:	NA		

Products of Combustion: NA

Fire Hazards in the Presence of Various Substances: None

Explosion Hazards in the Presence of Various Substances: - Risk of explosion of the product in presence of mechanical impact: NA - Risk of explosion of the product in presence of static discharge: NA

Firefighting Media and Instructions: NG

Firefighting Equipment: Water

Protective Clothing (fire): Use extinguishing media suitable for surrounding materials

Special Remarks on Fire Hazards: None

---

#### 6. ACCIDENTAL RELEASE MEASURES

Clean up: Wear recommended personal protective equipment. Use absorbent towels or booms to clean up spills. Wipe surfaces clean and wash with soap and water.

---

#### 7. HANDLING AND STORAGE

When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Store product at room temperature 20 to 25C(68-77 F)

---

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### ENGINEERING CONTROLS:

Under indicated use, general room ventilation is usually satisfactory. Use local exhaust ventilation when necessary.

### PERSONAL PROTECTION:

Respirators: With satisfactory ventilation, respiratory protection not usually required.

Eyes: Safety glasses or goggles recommended.

Gloves: Disposable latex (or other appropriate) gloves

Clothing: Disposable garments if direct skin contact is anticipated.

---

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance, other characteristics: Lyophilized powder

Boiling Point:	NA	Vapor Density:	NA
Melting Point:	No clean point	Percent Volatiles:	NA
Freezing Point:	NG	pH:	5-6
Vapor Pressure:	NA	Molecular Weight:	1292.27
Note:	None	Solubility:	More than 200mg/mL
Color:	White to yellowish	Odor:	None noted
Specific Gravity:	NG	LogK:	NE

---

## 10. STABILITY AND REACTIVITY

Stability: Stable

Conditions/Materials to Avoid: None

Hazardous Polymerization: Will not occur

---

## 11. TOXICOLOGY INFORMATION

INGREDIENT NAME	TEST	RESULT	ROUTE	SPECIES
Micafungin Sodium	LD50	125mg/kg	IV	Male rats
Micafungin Sodium	LD50	250mg/kg	IV	Female rats
Micafungin Sodium	LD50	>200mg/kg	IV	Male and Female dogs

**SIGNS & SYMPTOMS OF OVEREXPOSURE MAY INCLUDE:**

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert, these may include:nausea, headache, diarrhea, pruritits and bilirubinemia. Occupational exposure has not been fully investigated.

**MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE:**

Pre-existing skin and respiratory conditions.

IMMEDIATE EFFECTS: Eye, skin and respiratory irritation may occur.

---

**12. ECOLOGICAL INFORMATION**

INGREDIENT NAME	SPECIES	PERIOD	RESULT
** Not Available **			

BOD and COD: NA  
Biodegradable/OECD: Not available  
Mobility: Not available  
Products of Degradation: The product itself and its products of degradation are not toxic  
Toxicity of the Products of Biodegradation: Not available  
Special Remarks on the Products of Biodegradation: Not available

---

**13. WASTE DISPOSAL**

Waste Disposal: Waste product should be incinerated in accordance with all federal, state and local regulations

---

**14. TRANSPORT INFORMATION**

REGULATORY INFORMATION	UN Number	Proper Shipping	Class
United States (DOT)	Not regulated		
PACKING GROUP:		LABEL:	
ADDITIONAL INFORMATION:			
Canada (TDG)	Not regulated		
PACKING GROUP:		LABEL:	
ADDITIONAL INFORMATION:			
Mexico (NOM-004-SCT2-1994)	Not regulated		
PACKING GROUP:		LABEL:	
ADDITIONAL INFORMATION:			

NAERG: NA


---

## 15. REGULATORY INFORMATION

HCS Classification:	Not controlled under HCS (US)
U.S. Federal Regulations:	TSCA 8(b) inventory: All components listed Clean Water Act (CWA) 307: No products were found Clean Water Act (CWA) 311: Sodium Hydroxide Clean Air Act (CAA) 112 accidental release prevention: No products were found Clean Air Act (CAA) 112 flammable substances: No products were found Clean Air Act (CAA) 112 toxic substances: No products were found SARA 302/304/311/312 extremely hazardous substances- No products found SARA 302/304 emergency planning and notification: no products were found SARA 302/304/311/312 hazardous chemicals: No products were found SARA 311/312 MSDS distribution- chemical inventory-hazard identification: No products were found
<u>SARA 313:</u> Form R - Reporting Requirements:	No products were found
Supplier Notification:	No products were found
State Regulations:	Pennsylvania RTK: Sodium hydroxide: (environmental hazard, generic environmental hazard) Massachusetts RTK: Sodium hydroxide New Jersey: Sodium hydroxide California prop 65: No products were found
WHMIS (Canada): Classification of the Degree of Risk (Mexico):	Not controlled under WHMIS (Canada) CEPA DSL: All components listed No hazardous ingredient

---

## 16. OTHER INFORMATION

National Fire Protection Association (U.S.A)		<u>Hazards</u> Fire: 0 Health: 1 Reactivity: 0 Special:
--	---	---

Label Requirements:	Follow good industrial hygiene practice
References:	

Abbreviations:

ACGIH: American Conference Of Governmental Industrial Hygienists

HEPA: High-Efficiency Particulate Air

IARC: International Agency for Research on Cancer

NA: Not Applicable

NE: Not Established

NG: Not Given

NIOSH: National Institute for Occupational Safety and Health

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit

PPM: Parts Per Million

QS: Quantity Sufficient

RCRA: Resource Conservation and Recovery Act

STEL: Short Term Exposure Limit

TLV: Threshold Limit Value

---