

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

Section 1 - Identification

- (a) **Product Identifier:** Micafungin for Injection
- (b) **NDC:** 25021-190-10, 25021-190-11, 25021-191-10, 25021-191-11, 25021-190-12, 25021-191-12
- Common/Trade Name:** Mycamine
- Chemical Name:** 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 Family:** Echinocandin antifungal
- (c) **Product Use:** Pharmaceutical used as an anti-infective.
- Product Type:** Regulated Prescription Drug
- Container Information:** Lyophilized Powder Vial
- (d) **Distributor:** Sagent Pharmaceuticals, 1515 E Woodfield Road Suite 1100, Schaumburg, IL 60173, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** Not classified.
- (b) **Signal Word,**
Hazard statement(s),
Symbol(s), and/or Not applicable.
Precautionary
statement(s):
- (c) **Description of Hazards:** No known significant effects or critical hazards.
- (d) **Unknown Acute Toxicity:** Not applicable.

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Micafungin	Mycamine	98.5	208538-73-2	N/A

Section 4 - First Aid Measures

Eye Exposure:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Skin Exposure:	Wash with soap and water.
Ingestion:	Rinse mouth with water. Never give anything through mouth to an unconscious person. Get medical attention if you feel unwell.
Injection:	N/A
Inhalation:	If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.
Notes to Physician:	See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

(a) Extinguishing Media	Carbon dioxide, dry chemical powder, water spray.
(b) Hazardous Combustion Products:	In case of heating or fire, toxic gases maybe released, carbon dioxide, nitric oxide.
(c) Special Protective Equipment / Precautions:	Wear suitable self-contained breathing apparatus and chemical-protective clothing. Firefighting the winds direction.

Section 6 - Accidental Release Measures

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 2 of 8
------------------------------------	--	----------------------------

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

Spill: Pick up mechanically. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Release to Air: Evacuate area. Do not breathe dust. Avoid dust formation

Release to Water: Do not let product enter drains.

Section 7 - Handling and Storage

General Handling: Do not handle until all safety precautions have been read and understood. Provide appropriate exhaust ventilation at places where amounts of dust is formed. Use in a well-ventilated area. Normal measures for preventive fire protection. Use personal protective equipment as required. Wash hands before breaks and after work. Do not eat drink or smoke in the workplace.

Storage Conditions: Unopened vials of lyophilized material must be stored at room temperature, 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.] Protect from light.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Micafungin	N/A	N/A	N/A

(b) Engineering Controls

Ventilation: Provide adequate exhaust ventilation in the workplace.

(c) Individual Protection Measures

Respiratory Protection:	Use suitable respiratory protective device in case of insufficient ventilation.
Eye Protection:	Wear appropriate eye/face protection if necessary.
Skin Protection:	Wear protective gloves as required.
Other Protective Equipment:	Wear protective gloves as required.

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 3 of 8
------------------------------------	--	----------------------------

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

Additional Exposure Precautions:	Wear suitable self-contained breathing apparatus and chemical-protective clothing. Firefighting the wind's direction.
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Section 9 - Physical and Chemical Properties

(a)	Appearance	White lyophilized, powder
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	5-7
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	white powder that is freely soluble in water, isotonic sodium chloride solution, N,N-dimethylformamide and dimethylsulfoxide, slightly soluble in methyl alcohol, and practically insoluble in acetonitrile, ethyl alcohol (95%), acetone, diethyl ether and n-hexane
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Product is non-igniting
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 4 of 8
------------------------------------	--	----------------------------

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

(a)	Reactivity	No specific test data related to reactivity available for this product or its ingredients.
(b)	Chemical Stability	Stable under normal handling and storage conditions.
(c)	Possibility of Hazardous Reactions	No hazardous reactions known.
(d)	Conditions to Avoid	Flames, sparks, heating and other sources of ignition.
(e)	Incompatible Materials	Not available
(f)	Hazardous Decomposition Products	In case of heating or fire, toxic gases may be released: carbon oxides, nitric oxide.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	No data available.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	No data available.

(d) Acute Toxicity:

Carcinogenesis - 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.

Mutagenicity - Micafungin sodium was not mutagenic or clastogenic when evaluated in a standard battery of in vitro and in vivo tests

Impairment of fertility - There was no impairment of fertility in animal studies with micafungin sodium.

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

NIOSH: No

Section 12 - Ecological Information

(a)	Ecotoxicity	No data available
(b)	Persistence and degradability	No data available
(c)	Bioaccumulative potential	No data available
(d)	Mobility in soil	No data available

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 5 of 8
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	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

(e)	Other Adverse Effects	No data available
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Section 13 - Disposal Considerations

Disposal must be made according to local and national regulations.

Section 14 - Transport Information

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: Not regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: No
CERCLA: Not on this list
SARA 302: Not on this list
SARA 313: Not on this list
CA Prop 65 : Not on this list

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Sagent Pharmaceuticals
1515 E Woodfield Road Suite 1100, Schaumburg, IL 60173
847-908-1600

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 6 of 8
------------------------------------	--	----------------------------

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection		
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025	

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 7 of 8
------------------------------------	--	----------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Micafungin for Injection	
	Document No. MSDS-0119	Version 3.0	Effective Date 26 May 2025

USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)