
	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Caspofungin Acetate for Injection	
	Document No. MSDS-0137	Version 1.0	Effective Date 06 Jun 2023

Section 1 - Identification

- (a) **Product Identifier:** Caspofungin Acetate for Injection
- (b) **NDC:** 25021-194-10, 25021-195-10
- Common/Trade Name:** Cancidas
- Chemical Name:** 1-[(4R,5S)-5-[(2-aminoethyl)amino]-N2-(10,12-dimethyl-1-oxotetradecyl)-4-hydroxy-L-ornithine]-5-[(3R)-3-hydroxy-L-ornithine] pneumocandin B0 diacetate (salt)
- Chemical Family:** Echinocandin Antifungal
- (c) **Product Use:** Antifungal Drug
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Sagent Pharmaceuticals, 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** **NFPA Rating**
Health Hazard: 0
Fire Hazard: 0
Reactivity Hazard: 0
- (b) **Signal Word,** N/A
Hazard statement(s),
Symbol(s), and/or
Precautionary
statement(s):
- (c) **Description of Hazards:** N/A
- (d) **Unknown Acute Toxicity:** N/A

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Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	(c) CAS No.	(d) Impurities / Stabilizing Additives
1-[(4R,5S)-5-[(2-aminoethyl)amino]-N2-(10,12-dimethyl-1-oxotetradecyl)-4-hydroxy-L-ornithine]-5-[(3R)-3-hydroxy-L-ornithine] pneumocandin B0 diacetate	Caspofungin	179463-17-3	N/A
(2R,3R,4R,5R)-Hexan-1,2,3,4,5,6-hexol	Mannitol	69-65-8	N/A
beta-DFructofuranosylalpha-Dglucopyranoside	Sucrose	57-50-1	N/A
Acetic acid, glacial, Ethanoic acid	Glacial acetic acid	64-19-7	N/A
Sodium hydroxide	Sodium hydroxide	1310-73-2	N/A
Water	Water for Injection	7732-18-5	N/A

Section 4 - First Aid Measures

Eye Exposure:	Flush eyes with water as a precaution. Get medical attention if irritation or signs of exposure are noted.
Skin Exposure:	Remove contaminated clothing, wash skin with soap and water. Get medical attention if irritation or signs of exposure are noted.
Ingestion:	Do not induce vomiting. Call a physician or Poison Control Center. Rinse mouth with plenty of water. Never give anything by mouth to an unconscious person. Get medical attention immediately.
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

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- (a) **Extinguishing Media** Water spray, alcohol-resistant foam, dry chemical, carbon dioxide
- (b) **Hazardous Combustion Products:** Formed under fire conditions: Carbon and Nitrogen oxides
- (c) **Special Protective Equipment / Precautions:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Prevent spillage, do not let product enter drains.
- Release to Air:** N/A
- Release to Water:** Do not let product enter drains.


Section 7 - Handling and Storage

- General Handling:** Gloves, mask and goggles are recommended during handling.
- Storage Conditions:** Store refrigerated between 2° and 8°C (36° and 46°F). Discard unused portion.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Caspofungin	OSHA	TWE	NE
	OSHA	STEL	NE
	ACGIH	TWE	NE
	ACGIH	STEL	NE
	OEL	TWE	NE
	OEL	STEL	NE
Mannitol	-	-	N/A
Sodium hydroxide	OSHA	PEL	NE (2mg/m3)

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	ACGIH	TLV	NE (2mg/m3, Ceiling)
	AIHA	WEEL	NE (8 hr TWA)


(b) Engineering Controls: N/A

(c) Individual Protection Measures

Respiratory Protection:	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Eye Protection:	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
Skin Protection:	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Other Protective Equipment:	N/A
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

Section 9 - Physical and Chemical Properties

(a)	Appearance	A white to off-white lyophilized cake/powder.
(b)	Odor	N/A
(c)	Odor Threshold	N/A
(d)	pH	6.0 – 7.0
(e)	Melting Point:	N/A
(f)	Initial Boiling Point:	N/A
(g)	Flash Point	N/A
(h)	Evaporation Rate:	N/A
(i)	Flammability	N/A

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(j)	Upper Lower Flammability or Explosion Limits	N/A
(k)	Vapor Pressure:	N/A
(l)	Vapor Density:	N/A
(m)	Relative Density	N/A
(n)	Solubility(ies)	Soluble in water.
(o)	Partition Coefficient: n-octanol/water	N/A
(p)	Auto-ignition Temperature	N/A
(q)	Decomposition Temperature	N/A
(r)	Viscosity	N/A

Section 10 - Stability and Reactivity


(a)	Reactivity	N/A
(b)	Chemical Stability	Stable under recommended storage conditions.
(c)	Possibility of Hazardous Reactions	N/A
(d)	Conditions to Avoid	N/A
(e)	Incompatible Materials	Strong oxidizing agents.
(f)	Hazardous Decomposition Products	Carbon oxides, nitrogen oxides

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	<p>In clinical use, non-hemorrhagic adverse effects include:</p> <p>Adults: Most common adverse reactions are diarrhea, pyrexia, ALT/AST increased, blood alkaline phosphates increased, and Blood potassium decreased.</p> <p>Pediatric patients: Most common adverse reactions are pyrexia, diarrhea, rash, ALT/AST increased, blood potassium decreased, hypotension, and chills.</p>
(c)	Delayed and immediate effects and also chronic effects from short- and long-term exposure	Rash, facial swelling, angioedema, pruritus, sensation of warmth, or bronchospasm.

(d) Acute Toxicity

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Component	Type	Route	Species	Dosage
Caspofungin	LD ₅₀	Dermal	Rabbit	> 500mg/kg
Mannitol	LD ₅₀	Oral	Rat	13500 mg/kg
Sodium Hydroxide	LD ₅₀	Oral	Rabbit	500 mg/kg

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

NIOSH: No

(f) Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: No long-term studies in animals have been performed to evaluate the carcinogenic potential of Caspofungin.

Mutagenesis: Caspofungin did not show evidence of mutagenic or genotoxic potential when evaluated in the following *in vitro* assays: bacterial (Ames) and mammalian cell (V79 Chinese hamster lung fibroblasts) mutagenesis assays, the alkaline elution/rat hepatocyte DNA strand break test, and the chromosome aberration assay in Chinese hamster ovary cells. Caspofungin was not genotoxic when assessed in the mouse bone marrow chromosomal test at doses up to 12.5 mg/kg (equivalent to a human dose of 1 mg/kg based on body surface area comparisons), administered intravenously.


Impairment of Fertility: Fertility and reproductive performance were not affected by the intravenous administration of Caspofungin to rats at doses up to 5 mg/kg. At 5 mg/kg exposures were similar to those seen in patients treated with the 70 mg dose.

Section 12 - Ecological Information

(a)	Ecotoxicity	LC50(Fish- Fathed minnow -96 h) = 0.3 mg/l LC50(Algae- S.Capricornutum-96 h) = 0.1mg/l
(b)	Persistence and degradability	Hydrolyzes slowly.
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	N/A
(e)	Other Adverse Effects	N/A

Section 13 - Disposal Considerations

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Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14 - Transport Information

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

DOT: Not dangerous goods.

ICAO/IATA: Not dangerous goods.

IMDG: Not dangerous goods.

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: Not on this list

CERCLA: Not on this list

SARA 302: Not on this list

SARA 311/312: Hazard categories:

Fire: No

Pressure Generating: No

Reactivity: No

Acute: Yes

Chronic: No


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

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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

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Schaumburg, IL 60195

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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

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