

**SAFETY DATA SHEET****SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY**

- a) **Product Name** : Caspofungin acetate for Injection (50mg/Vial)
- b) **Common/Trade Name** : Caspofungin acetate for Injection (50mg/Vial)
Chemical Names : 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
- Chemical Family** : Echinocandin derivatives
- c) **Product Use** : Antifungal drug
Product Type : Regulated Prescription Drug
Container Information : Vial
- d) **Manufacturers Name & Address** : **Gland Pharma Limited**
: Survey No.: 143–148, 150&151
: Near Gandimaisamma Cross Roads,
: D.P.Pally, Quthbullapur Mandal
: Ranga Reddy District
: Hyderabad- 500043
: Telangana, India
- e) **Telephone Number for Info** : +91-40-30510999

SECTION 2 – HAZARDS IDENTIFICATIONa) **Classification****NFPA Rating**

Health Hazard	:	0
Fire Hazard	:	0
Reactivity Hazard	:	0

b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	c) Description of Hazards:
Signal Word: Not Available	Not Available
Not a dangerous substance	

d) **Unknown Acute Toxicity:** N/A



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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

a) Chemical Name	b) Common Name/Synonym	%Composition or other measure	c) CAS Number	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	54.6 mg/Vial	179463-17-3	N/A
(2R,3R,4R,5R)-Hexan-1,2,3,4,5,6-hexol	Mannitol	26 mg/Vail	69-65-8	N/A
beta-D-Fructofuranosyl-alpha-Dglucopyranoside	Sucrose	39 mg/Vial	57-50-1	N/A
Acetic acid, glacial, Ethanoic acid	Glacial acetic acid	q.s for pH adjustment	64-19-7	N/A
Sodium hydroxide	Sodium hydroxide	q.s for pH adjustment	1310-73-2	N/A
Water	Water for Injection	q.s.to 1.82 mL	7732-18-5	N/A

SECTION 4 – FIRST AID MEASURES

- Eye Exposure** : Flush eyes with water as a precaution.
- Skin Exposure** : Wash off with soap and plenty of water.
- 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 breathed in, move person into fresh air. If not breathing, give artificial respiration.
- Notesto Physician** : See patient package insert in shipping carton for complete information



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SECTION 5 – FIRE FIGHTING MEASURES

- 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** : Wear self-contained breathing apparatus

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Spill : Prevent spillage, do not let product enter drains

Release to Air : NA

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 at 2°C to 8°C (36°F to 46°F).

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Caspofungin	OSHA	TWE	NE
	OSHA	STEL	NE
	ACGHI	TWE	NE
	ACGHI	STEL	NE
	OEL	TWE	NE
	OEL	STEL	NE
Mannitol	--	--	NA
Sodium hydroxide	OSHA	PEL	NE (2mg/m ³)
	ACGIH	TLV	NE (2mg/m ³ , Ceiling)
	AIHA	WEEL	NE (8 hr TWA)

(b) **Engineering Controls** Not available



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(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. They type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

a)	Appearance/Description	:	A white to off white lyophilized cake/powder.
b)	Odor	:	NA
c)	Odor Threshold	:	NA
d)	pH	:	6.0-7.0
e)	Melting Point	:	NA
f)	Initial Boiling Point	:	NA
g)	Flash Point	:	NA
h)	Evaporation Rate	:	NA
i)	Flammability	:	NA
j)	Upper Lower Flammability or Explosion Limits	:	NA
k)	Vapor Pressure:	:	NA
l)	Vapor Density	:	NA
m)	Relative Density	:	NA
n)	Solubility(ies)	:	Soluble in water
o)	Partition Coefficient: n-octanol/water	:	NA
p)	Auto-ignition Temperature	:	NA
q)	Decomposition Temperature	:	NA
r)	Viscosity	:	NA



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SECTION 10 – STABILITY AND REACTIVITY

a)	Chemical Stability	Stable under recommended storage conditions.
b)	Conditions to Avoid	No data available
c)	Incompatible Materials	Strong oxidizing agents
d)	Hazardous Decomposition Products	Carbon oxides, nitrogen oxides

SECTION 11 – TOXICOLOGICAL INFORMATION

a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion
b)	Symptoms related to the physical, chemical and toxicological characteristics	In clinical use, non-hemorrhagic adverse effects include Adults: Most common adverse reactions are diarrhea, pyrexia, ALT/AST increased, blood alkaline phosphates increased, and Blood potassium decreased. • Pediatric patients: Most common adverse reactions are pyrexia, diarrhea, rash, ALT/AST increased, blood potassium decreased, hypotension, and chills.
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:

Component	Type	Route	Species	Dosage
Caspofungin	LD50	Dermal	Rabbit	>500mg/kg
Mannitol	LD50	Oral	Rat	13500 mg/kg
Sodium Hydroxide	LD50	Oral	Rabbit	500mg/kg

Reproductive Effects: Decrease in fetal body weights and an increase of incomplete ossification of the skull and torso. Increase in the cervical rib in rats. Has been shown to cross the placental barrier in animal studies.

e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: carcinogen.

SECTION 12 – ECOLOGICAL INFORMATION

a)	Ecotoxicity	LC50(Fish- Fathed minnow -96 h) = 0.3 mg/l LC50(Algea- S.Capricornutum-96 h) = 0.1mg/l
b)	Persistence and degradability	Hydrolyzes slowly
c)	Bioaccumulative potential	Not established
d)	Mobility in soil	Not established
e)	Other Adverse Effects	Not established



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SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal & Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

SECTION 14 – TRANSPORTATION INFORMATION

a)	UN Number	Not available
b)	UN Proper Shipping Name	Not available
c)	Transport Hazard Class(es)	Not available
d)	Packing Group	Not available
e)	Environmental Hazards	Not available
f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
g)	Special Precautions	Not available

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 usage. 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 311/312 Hazard categories – Fire: No Pressure Generating: No Reactivity: No Acute: Yes

Chronic: No

SARA 313 - Not on this list

Prop 65 (Calif.) – Not on this list



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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.



SAFETY DATA SHEET

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