 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 1 of 10


Section 1 - Identification


- (a) **Product Identifier:** Caspofungin Acetate for Injection
- (b) **Product Code:** 70860-106, 70860-107
- Common/Trade Name:** Caspofungin
- 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:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Not Available

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

GHS Signal Word:	DANGER
GHS Hazard Statement:	<ul style="list-style-type: none"> ▪ H318: Causes serious eye damage. ▪ H361: Suspected of damaging fertility or the unborn child. ▪ H372: Causes damage to organs through prolonged or repeated exposure. ▪ H400: Very toxic to aquatic life.
GHS Symbols:	

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 2 of 10

GHS Precautionary Statements:	<p>Prevention:</p> <ul style="list-style-type: none"> ▪ P201 Obtain special instructions before use. ▪ P273 Avoid release to the environment. ▪ P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. <p>Response:</p> <ul style="list-style-type: none"> ▪ P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician. ▪ P308 + P313 IF exposed or concerned: Get medical advice/ attention. ▪ P391 Collect spillage.
Other Hazards	<ul style="list-style-type: none"> ▪ Potential dust explosion hazard. ▪ Contact with dust can cause mechanical irritation or drying of the skin.


(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

50 mg Vial

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(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 (salt)	Caspofungin	54.6 mg	179463-17-3	N/A
Sucrose	Table Sugar	39 mg	57-50-1	N/A
Mannitol	Mannitol	26mg	69-65-8	N/A
Glacial Acetic Acid	Glacial Acetic Acid	*	64-19-7	N/A
Sodium Hydroxide	Sodium Hydroxide	*	1310-73-2	N/A

*Used for pH adjustment

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 3 of 10


70 mg Vial

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(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 (salt)	Caspofungin	75.6 mg	179463-17-3	N/A
Sucrose	Table Sugar	54 mg	57-50-1	N/A
Mannitol	Mannitol	36 mg	69-65-8	N/A
Glacial Acetic Acid	Glacial Acetic Acid	*	64-19-7	N/A
Sodium Hydroxide	Sodium Hydroxide	*	1310-73-2	N/A

*Used for pH adjustment

Section 4 – First Aid Measures

Emergency Overview	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Eye Exposure:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
Skin Exposure:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
Ingestion:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Injection:	In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
Inhalation:	If inhaled, remove to fresh air. Get medical attention.
Notes to Physician:	Treat symptomatically and supportively.


 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 4 of 10

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
- (b) **Hazardous Combustion Products:** Carbon oxides
Note: Do not use a solid water stream as it may scatter and spread fire. Exposure to combustion products may be a hazard to health.
- (c) **Special Protective Equipment / Precautions:** In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Section 6 - Accidental Release Measures

- Spill:** Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Release to Air:** Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Release to Water:** Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 5 of 10

Section 7 - Handling and Storage

- General Handling:**
- Do not breathe dust.
 - Do not swallow.
 - Do not get in eyes.
 - Avoid prolonged or repeated contact with skin.
 - Handle in accordance with good industrial hygiene and safety practice.
 - Keep container tightly closed.
 - Minimize dust generation and accumulation.
 - Keep container closed when not in use.
 - Keep away from heat and sources of ignition.
 - Take care to prevent spills, waste and minimize release to the environment.
 - Static electricity may accumulate and ignite suspended dust causing an explosion.
 - Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
 - Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Storage Conditions: The lyophilized vials should be stored refrigerated at 2° to 8°C (36° to 46°F).


Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Caspofungin	OSHA	PEL	NE
	ACGIH	TWA	NE

(b) Engineering Controls

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).


 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 6 of 10

(c) Individual Protection Measures

Respiratory Protection:	Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
Eye Protection:	Chemical resistant goggles must be worn. If splashes are likely to occur, wear a face-shield.
Skin Protection:	Use impervious gloves. Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Other Protective Equipment:	Filter Type: Particulates type (P)
Additional Exposure Precautions:	None

Section 9 - Physical and Chemical Properties

(a) Appearance	White to off-white powder
(b) Odor	No odor
(c) Odor Threshold	Not available
(d) pH	6.6
(e) Melting Point:	Not available
(f) Initial Boiling Point:	153°C
(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

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 7 of 10

(n)	Solubility(ies)	Freely soluble in water and methanol, and slightly soluble in ethanol
(o)	Partition Coefficient: n-octanol/water	log Pow: -1.6
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not classified as a reactivity hazard.
(b)	Chemical Stability	Stable at normal temperature and pressures.
(c)	Possibility of Hazardous Reactions	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
(d)	Conditions to Avoid	None known
(e)	Incompatible Materials	Oxidizing agents
(f)	Hazardous Decomposition Products	No hazardous decomposition products are known.


Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, ingestion, skin contact or eye contact.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye damage. Suspected of damaging the unborn child.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	Causes serious eye damage. Suspected of damaging the unborn child.

(d) Acute Toxicity

Based on available data, the classification criteria are not met.

Component	Type	Route	Species	Dosage
Caspofungin	LD ₅₀	Oral	Mouse	>2,000 mg/kg

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 8 of 10

(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed **ACGIH:** Not Listed

Section 12 - Ecological Information

(a) Ecotoxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
(b) Persistence and degradability	Not Available.
(c) Bioaccumulative potential	Not Available
(d) Mobility in soil	Not available
(e) Other Adverse Effects	Not Available


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(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

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 9 of 10

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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 regulated
 CERCLA - Not on this list
 SARA 302 - Not on this list
 SARA 311/312: Not on this list
 SARA 313 - Not on this list
 OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, 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:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

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
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency

 Pharmaceutical Division	Caspofungin Acetate for Injection		Safety Data Sheet (SDS)	
	Effective Date: 22DEC2017	SDS No.: SDS017	Revision No: 02	Page 10 of 10

EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS017

Revision: 02

Title: Caspofungin Acetate for Injection

All dates and times are in Eastern Standard Time.

APD-PACKET-00142

Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	21 Dec 2017, 04:54:05 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	22 Dec 2017, 12:50:47 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
LaShaun Maxie (LMAXIE)	Director of Quality Assurance	22 Dec 2017, 01:13:16 PM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Quality	22 Dec 2017, 01:23:54 PM	Approved