SAFETY DATA SHEET

PRODUCT NAME: CANCIDAS® FOR INJECTION **Page: 1/7**

Revision 25-Aug-2008

1. Product and Company Identification

Manufactured/Supplied by	MERCK & CO., INC. One Merck Drive Whitehouse Station, NJ 08889-0100 (908) 423-1000 Emergency Telephone Number: 1-732-594-5555
Label Name	CANCIDAS® FOR INJECTION
Chemical Name	**Caspofungin Acetate:** 1-[(4R,5S)-5-[(2-aminoethyl)amino]-N2-(10,12-dimethyl-1-oxotetra hydroxy-L-ornithine]-5-[(3R)-3-hydroxy-L-ornithine]pneumocandin B0 diacetate (salt)
Synonyms	INTRAVENOUS INFUSION (not for IV Bolus Injection) CANCIDAS® (caspofungin acetate) FOR INJECTION; Caspofungin acetate (MK-0991)
Material Product Number	3822 (50 mg) **NDC** 0006-3822-10 3823 (70 mg) **NDC** 0006-3823-10
Intended Use	Finished pharmaceutical product. Anti-fungal agent.

2. Composition/Information on Ingredients

Component	Molecular Formula	Molecular weight	CAS Number	Percent (%)
CASPOFUNGIN ACETATE	C52H88N10O15·2C2H4O2	1213.42	179463-17-3	47
ACETIC ACID	C2H4O2	60.05	64-19-7	1.5
SODIUM HYDROXIDE	NaOH	40	1310-73-2	1
Inactive ingredients		Not established		50.5

Irritant, Dangerous for the environment

EC Label

R38- Irritating to skin.
R41- Risk of serious damage to eyes.
R50- Very toxic to aquatic organisms.

3. Hazards Identification

Appearance	White to off white powder/cake
Label Text	WARNING! No specific hazard with intact vials. If potential exists for direct exposure, causes severe eye irritation. Very toxic to aquatic organisms.
Emergency Overview	Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Avoid contact of spilled material and runoff with soil and surface waterways.
Potential Health Effects	See Section 11 for detailed information.

***** Continued on next page *****

4. First Aid Measures

Eye Contact	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.
Skin Contact	Wash with soap and water. Get medical attention if irritation develops.
Inhalation	If inhaled, remove to fresh air. If not breathing, give CPR (cardiopulmonary resuscitation). If breathing is difficult, give oxygen. Get medical attention immediately.
Ingestion	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
Notes to physician	For additional guidance refer to the current prescribing information or the local poison control center.

5. Fire Fighting Measures

Flash Point	Not applicable.
Flammable Limits (% in air)	Not applicable.
Autoignition Temperature	Not applicable.
Oxidizing Properties	None known.
Combustibility Information	Not available.
Dust Explosivity Information	**CASPOFUNGIN ACETATE** Minimum Ignition Energy (MIE) 100 mJ<MIE<300 mJ Without inductance 30 mJ<MIE< 100mJ With inductance
Shock Sensitivity	None.
Fire/Explosion Hazards	Not available.
Special Fire Procedures	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Extinguishing Media	Use foam or all purpose dry chemicals to extinguish. This material is very toxic to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
Hazardous Decomposition Products	These products are carbon oxides, nitrogen oxides. Some metallic oxides.

6. Accidental Release Measures

Personal Precautions	**See Section 8 for Personal Protective Equipment.** Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).

***** Continued on next page *****

Methods for cleaning up

If emergency personnel are unavailable vacuum or carefully scoop up spilled materials and place in an appropriate container for disposal. Avoid creating dusty conditions and prevent wind dispersal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. **See Section 13 for Waste Disposal Information.**

7. Handling and Storage

Handling

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Avoid contact of spilled material and runoff with soil and surface waterways.

Storage

Keep container tightly closed. Keep container in a cool, well-ventilated area

The lyophilized vials should be stored refrigerated at 2º to 8ºC (36º to 46ºF).

8. Exposure Controls/Personal Protection

Exposure Guidelines

Component	OSHA Permissible Exposure Limit (PEL)	ACGIH Threshold Limit Value (TLV)	Merck Exposure Control Limit (ECL) or PB-ECL Category
CASPOFUNGIN ACETATE	Not established	Not established	0.075 mg/m^3 (TWA)
ACETIC ACID	10 ppm (TWA)	10 ppm (TWA) 15 ppm (STEL)	Not established
SODIUM HYDROXIDE	2 mg/m^3 (TWA)	2 mg/m^3 (CEIL)	Not established
Inactive ingredients	Not established	Not established	Not established

Engineering Controls

None required with normal handling of finished product.

Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the powders to uncontrolled areas (e.g., open-face containment devices).

Personal Protective Equipment

Eye/Face Protection

None required with normal handling of finished product.

Safety glasses with side shields. Where the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin Protection

None required with normal handling of finished product.

Disposable chemical resistant gloves. Consider double gloving. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

***** Continued on next page *****

Respiratory Protection	None required with normal handling of finished product. Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. When handling a compound in solution, a cartridge/canister appropriate for the solution may also be needed. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabiliites, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.
Additional Protective Equipment	No special recommendations. Standard asceptic techniques should be followed for preparation of product.

9. Physical and Chemical Properties

Appearance	White to off white powder/cake
Odor/Threshold Limit	**ACETIC ACID** Strong, pungent, vinegar-like odor. (Strong) /0.21 to 1 ppm
pH	The pH of a saturated aqueous solution of caspofungin acetate is approximately 6.6.
Boiling Point	Not applicable.
Melting Point	**CASPOFUNGIN ACETATE** 153°C (307.4°F)
Flash point	Not applicable.
Flammable Limits (% in air)	Not applicable.
Autoignition Temperature	Not applicable.
Solubility	Easily soluble in cold water.
Partition Coefficient	**CASPOFUNGIN ACETATE** Log Kow: -1.6
Specific Gravity	Not applicable.
Vapor Density	Not applicable.
Vapor Pressure	Not applicable.
Volatility Component	0% (w/w).

10. Stability and Reactivity

Stability	The product is stable.
Conditions to Avoid	None known.
Incompatibility	None known.
Hazardous Polymerization	Will not occur.
Hazardous Decomposition Products	These products are carbon oxides, nitrogen oxides. Some metallic oxides.

***** Continued on next page *****

11. Toxicological Information

Routes of Entry
Ingestion: No.
Inhalation: Unlikely
Skin Contact: No.

Toxicity Data

Component	Test	Species	Route	Result
CASPOFUNGIN ACETATE	LD50	Mouse	Oral	>2000 mg/kg
ACETIC ACID	LD50	Rat	Oral	3530 mg/kg
	LD50	Rabbit	Dermal	1060 mg/kg
	LC50	Mouse	Inhalation	5000 ppm (1 hour)
	LCLo	Rat	Inhalation	16000 ppm (4 hours)
SODIUM HYDROXIDE	LD50	Rabbit	Oral	500 mg/kg

Effects of Acute Exposure

Eye contact: Finished product expected to be severely irritating to the eyes.

Skin contact: Finished product expected to be slightly irritating to the skin.

Inhalation: None expected with normal handling of finished product.

Ingestion: Practically non-toxic if swallowed. In humans, the highest single dose of 210 mg was well tolerated.

Effects of Chronic Exposure: Contains material which can cause damage to the: lungs, upper respiratory tract, skin, eye, lens or cornea, teeth.

CASPOFUNGIN ACETATE The most common adverse effects reported in patients were fever, headache, infused vein complications, nausea, vomiting, flushing and chills. In humans, possible histamine-mediated symptoms have been reported including rash, facial swelling, itching, sensation of warmth, or bronchospasm. Anapylaxis has been reported. These effects have been reported in individuals receiving the drug intravenously and their relevance to workplace exposures is unknown. Liver function test abnormalities have occurred in healthy volunteers and patients receiving cancidas. Repeat-dose intravenous (IV) studies in animals resulted in systemic reactions attributed to histamine release and liver toxicity in the rat and monkey. Fertility and reproductive performance were not affected by the intravenous administration of caspofungin to rats. It was shown to cause adverse developmental effects in rats and rabbits and was found in the milk of lactating, drug-treated rats.

Carcinogen Designation: Not listed as a carcinogen by OSHA, NTP or IARC.

Medical Conditions Aggravated by Overexposure: Individuals with moderate liver insufficiency will be more sensitive.

***** Continued on next page *****

12. Ecological Information

Environmental Effects

Very toxic to aquatic organisms.

CASPOFUNGIN ACETATE: The EC10 for ASRIT is 38 mg/L. Concentrations less than this are not likely to impact unacclimated sludge sewage treatment systems.

Ecotoxicity Data

Component	Species	Period	Result
CASPOFUNGIN ACETATE	*Daphnia magna* (LC50)	48 hours	22.6 mg/L
	Daphnia magna (EC50)	48 hours	15 mg/L
	Fathead minnow (LC50)	96 hours	2.4 mg/L
	Fathead minnow (EC50)	96 hours	0.3 mg/L
	S. Capricornutum (LC50)	96 hours	0.1 mg/L

Environmental Fate

CASPOFUNGIN ACETATE: Hydrolyzes slowly at 21ºC (t 1/2 = 24.5 days). The half-life at 60ºC and pH = 8 is 1.45 hrs. Compound does not decompose by photolysis. High solubility and low Kow (-1.6) suggest little to no potential for bioaccumulation.

13. Disposal Considerations

Waste Disposal Information

Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spill residues includir contaminated soils following all applicable regulations.

14. Transport Information

Shipping Description

U.S. DOT: Not regulated.

IATA/ICAO: Not regulated.

IMO: Not regulated.

ADR/RID: Not regulated.

15. Regulatory Information

U.S. Federal Regulations

Hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200).

State Regulations

Not available.

International Regulations

Classified as Dangerous according to the Dangerous Substance Directive (DSD).

***** Continued on next page *****

16. Other Information

Revision: Engineering Controls, Personal Protective Equipment, Effects of Acute Exposure, Effects of Chronic Exposure, Medical Conditions Aggravated by Overexposure

Revision:	8/25/2008.
Date of Preparation	30-Nov-2000
Date of Previous Issue	6-Feb-2006
Validation Date	8/25/2008.
MSDS Coordinator:	1-908-423-7903 Merck & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889-0100

Disclaimer:

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.