

## Caspofungin Formulation

Version 5.1      Revision Date: 26.09.2023      SDS Number: 24273-00024      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Caspofungin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Serious eye damage : Category 1

Effects on or via lactation

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.  
H362 May cause harm to breast-fed children.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P260 Do not breathe dust.

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P273 Avoid release to the environment.  
 P280 Wear eye protection/ face protection.

**Response:**

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/ doctor.

P391 Collect spillage.

**Other hazards which do not result in classification**

May form explosive dust-air mixture during processing, handling or other means.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Caspofungin	179463-17-3	Serious eye damage, Category 1 Effects on or via lactation, Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 30 -< 50
Sucrose	57-50-1		>= 30 -< 50
Acetic acid	64-19-7	Flammable liquids, Category 3 Acute toxicity (Oral), Category 5 Skin corrosion, Category 1A Serious eye damage, Category 1	>= 1 -< 3

**SECTION 4. FIRST AID MEASURES**

General advice : 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.

If inhaled : Get medical attention.

In case of skin contact : Wash with water and soap.  
 Get medical attention.

In case of eye contact : 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.

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If swallowed	:	Get medical attention immediately.
Most important symptoms and effects, both acute and delayed	:	Get medical attention. Causes serious eye damage. May cause harm to breast-fed children.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

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**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. Local or national regulations may apply to releases and

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disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Avoid contact during pregnancy and while nursing.  
 Do not breathe dust.  
 Do not swallow.  
 Do not get in eyes.  
 Avoid prolonged or repeated contact with skin.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 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 precautionary measures against static discharges.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
 When using do not eat, drink or smoke.  
 Wash contaminated clothing before re-use.
- Conditions for safe storage : Keep in properly labeled containers.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Caspofungin	179463-17-3	TWA	140 µg/m <sup>3</sup> (OEB 2)	Internal
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	ACGIH
Acetic acid	64-19-7	LT	8 ppm 20 mg/m <sup>3</sup>	BR OEL

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	Further information: Degree of harmfulness: medium			
	TWA	10 ppm	ACGIH	
	STEL	15 ppm	ACGIH	

**Engineering measures** : 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).

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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 aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
 Chemical resistant goggles must be worn.  
 If splashes are likely to occur, wear:  
 Face-shield

Skin and body protection : 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).

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : off-white

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

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Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Minimum ignition energy	:	100 - 300 mJ 30 - 100 mJ
Particle size	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing,

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tions	handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg  
Method: Calculation method

#### Components:

##### Caspofungin:

Acute oral toxicity : LD50 (Mouse): > 2.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 19 mg/kg  
Application Route: Intravenous

LD50 (Rat): 38 mg/kg  
Application Route: Intravenous

##### Sucrose:

Acute oral toxicity : LD50 (Rat): 29.700 mg/kg

##### Acetic acid:

Acute oral toxicity : LD50 (Rat): > 2.000 - 5.000 mg/kg  
Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg  
Remarks: Based on data from similar materials

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Caspofungin:

Species : Rabbit

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Result : Mild skin irritation

**Acetic acid:**

Species : Rabbit  
Result : Corrosive after 3 minutes or less of exposure

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Caspofungin:**

Species : Rabbit  
Result : Irreversible effects on the eye  
Method : Bovine cornea (BCOP)

**Acetic acid:**

Species : Rabbit  
Result : Irreversible effects on the eye

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Caspofungin:**

Genotoxicity in vitro : Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster fibroblasts  
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Result: negative



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**Sucrose:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

**Acetic acid:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: equivocal  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: inhalation (vapor)  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:****Acetic acid:**

Species : Mouse  
Application Route : Skin contact  
Exposure time : 32 weeks  
Result : negative

**Reproductive toxicity**

May cause harm to breast-fed children.

**Components:****Caspofungin:**

Effects on fertility : Test Type: Fertility  
Species: Rat, male and female  
Application Route: Intravenous injection  
Fertility: NOAEL Parent: 5 mg/kg body weight  
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intravenous injection

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General Toxicity Maternal: LOAEL: 5 mg/kg body weight  
 Embryo-fetal toxicity.: NOAEL F1: 2 mg/kg body weight  
 Symptoms: Abnormalities of the musculoskeletal system.  
 Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Development  
 Species: Rabbit  
 Application Route: Intravenous injection  
 General Toxicity Maternal: NOAEL: 3 mg/kg body weight  
 Developmental Toxicity: NOAEL F1: >= 6 mg/kg body weight  
 Result: Embryotoxic effects and adverse effects on the offspring were detected.

Reproductive toxicity - Assessment : Studies indicating a hazard to babies during the lactation period

**Acetic acid:**

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Caspofungin:**

Species : Monkey  
 NOAEL : 2 mg/kg  
 LOAEL : 5 mg/kg  
 Application Route : Intravenous  
 Exposure time : 27 Weeks  
 Number of exposures : daily  
 Target Organs : Liver

Species : Rat  
 LOAEL : 1,8 mg/kg  
 Application Route : Intravenous  
 Exposure time : 27 Weeks  
 Symptoms : Swelling of tissue

Species : Rat  
 NOAEL : 2 mg/kg  
 LOAEL : 5 mg/kg  
 Application Route : Intravenous  
 Exposure time : 14 Weeks  
 Number of exposures : daily

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Symptoms : Swelling of tissue

**Acetic acid:**

Species : Rat  
 NOAEL : 290 mg/kg  
 Application Route : Ingestion  
 Exposure time : 8 Weeks

**Aspiration toxicity**

Not classified based on available information.

**Components:****Caspofungin:**

No aspiration toxicity classification

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Caspofungin:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 2,4 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 22,6 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0,1 mg/l Exposure time: 72 h
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0,05 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0,084 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,67 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1
Toxicity to microorganisms	:	EC50: > 127 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

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NOEC: 38 mg/l  
 Exposure time: 3 h  
 Test Type: Respiration inhibition  
 Method: OECD Test Guideline 209

**Acetic acid:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
 Exposure time: 96 h  
 Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202  
 Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
 Exposure time: 72 h  
 Remarks: Based on data from similar materials
- NOEC (Skeletonema costatum (marine diatom)): > 1 mg/l  
 Exposure time: 72 h  
 Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): > 1 mg/l  
 Exposure time: 21 d
- Toxicity to microorganisms : NOEC (Pseudomonas putida): 1.150 mg/l  
 Exposure time: 16 h

**Persistence and degradability****Components:****Caspofungin:**

- Biodegradability : Result: Not readily biodegradable.  
 Biodegradation: 71,9 %  
 Exposure time: 28 d  
 Method: OECD Test Guideline 302B
- Stability in water : Degradation half life (DT50): 2,8 h

**Acetic acid:**

- Biodegradability : Result: Readily biodegradable.  
 Biodegradation: 96 %  
 Exposure time: 20 d

**Bioaccumulative potential****Components:****Caspofungin:**

- Partition coefficient: n- : log Pow: -1,6

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octanol/water

**Sucrose:**

Partition coefficient: n-octanol/water : Pow: < 1

**Acetic acid:**

Partition coefficient: n-octanol/water : log Pow: -0,17

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Caspofungin)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Caspofungin)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

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(Caspofungin)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****ANTT**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.

(Caspofungin)  
Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION**

Revision Date : 26.09.2023  
Date format : dd.mm.yyyy

**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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