1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Caspofungin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
         Singapore - Singapore 638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation: Category 1
Reproductive toxicity: Category 2
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: ![Danger](image)

Signal word: Danger

Hazard statements:
H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ 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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caspofungin</td>
<td>179463-17-3</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

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: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: 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.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Most important symptoms and effects, both acute and delayed: Causes serious eye damage. Suspected of damaging the unborn child.

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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 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.

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:
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, 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.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
Keep in properly labelled containers.
Store locked up.
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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caspofungin</td>
<td>179463-17-3</td>
<td>TWA</td>
<td>100 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (long term)</td>
<td>25 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>TWA</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term)</td>
<td>15 ppm</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>37 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>15 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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 vapour type

Hand protection:

Material: Chemical-resistant gloves

Remarks: 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. 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).

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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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range

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
11. TOXICOLOGICAL INFORMATION

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.

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

Acute toxicity
Not classified based on available information.

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
- 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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
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
Species: Mouse
Cell type: Bone marrow
Result: negative

Sucrose:
Genotoxicity in vitro
Test Type: In vitro mammalian cell gene mutation test
Result: negative
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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 (vapour)
  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:
Suspected of damaging the unborn child.

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 foetal development:
- Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Intravenous injection
  General Toxicity Maternal: LOAEL: 5 mg/kg body weight
  Embryo-foetal 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: \( \geq 6 \) 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 foetal 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  
- NOAEL: 2 mg/kg  
- LOAEL: 5 mg/kg  
- Application Route: Intravenous  
- Exposure time: 14 Weeks  
- Number of exposures: daily  
- Symptoms: Swelling of tissue

**Acetic acid:**  
- Species: Rat  
- NOAEL: 290 mg/kg
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Caspofungin:
- No aspiration toxicity classification

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

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 fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): > 1 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 204

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-octanol/water: log Pow: -1.6

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

13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- Waste from residues: 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.

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

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Levels of Toxic Substances
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term
SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.