SAFETY DATA SHEET

Caspofungin Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 24288-00013  Date of last issue: 24.04.2019  Date of first issue: 21.10.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Caspofungin Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
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

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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:

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.
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

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</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.
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. Get medical attention immediately.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>TWA</td>
<td>10 ppm 25 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>15 ppm 37 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 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: 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 a 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

Appearance: powder

Colour: off-white

Odour: No data available

Odour Threshold: No data available

pH: No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
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.
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Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, 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.

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

**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:
- Test Type: Chromosomal aberration
  - Species: Mouse
  - Cell type: Bone marrow
  - Result: negative
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 (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: >= 6 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Reproductive toxicity - Assessment:
Some evidence of adverse effects on development, based on animal experiments.

Acetic acid:
Effects on foetal development:
Test Type: Embryo-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
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
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Number of exposures : daily
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

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 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

Toxicity to fish (Chronic toxicity) : NOEC: 0.084 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.67 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1

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
- NOEC (Skeletonema costatum (marine diatom)): > 1 mg/l
- Exposure time: 72 h
- Remarks: Based on data from similar materials

Toxicity to microorganisms:
- NOEC (Pseudomonas putida): 1,150 mg/l
- Exposure time: 16 h

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: > 1 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)

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
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
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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
Marine pollutant: yes

Transport in bulk according to IMO instruments
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

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)
IN OEL: India. Permissible levels of certain chemical substances in
work environment.

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL : Short-term exposure Limit STEL (15 min)

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals and Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN