SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Caspofungin Formulation

Manufacturer or supplier's details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage: Category 1
Reproductive toxicity: Category 2

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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 or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
Other hazards
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>Caspofungin</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
</tr>
<tr>
<td></td>
<td>Acetic acid</td>
</tr>
</tbody>
</table>

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: 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. 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.
SAFETY DATA SHEET

Caspofungin Formulation

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.

SECTION 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 spills 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.

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: Do not breathe dust. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin.
Safe and prudent practice is important when handling the Caspofungin Formulation. Ensure adequate ventilation, especially in confined areas. Keep workplaces free from dust. Use personal protective equipment as necessary. Do not store with strong oxidizing agents. Store away from heat and sources of ignition. Keep away from heat and sources of ignition. 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.

### 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. 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients 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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>VLE-PPT</td>
<td>10 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VLE-CT</td>
<td>15 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</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 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
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
Vapor pressure: No data available
Relative vapor density : No data available
Relative density : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition 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

SECTION 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.
   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
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

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  
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 fetal development:  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intravenous injection  
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: Some evidence of adverse effects on development, based on animal experiments.  


Acetic acid:
Effects on fetal development: Test Type: Embryofetal 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
Application Route: Intravenous
Exposure time: 14 Weeks
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
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
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
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
SECTION 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.

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

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
Subsidiary risk: ENVIRONM.
Packing group: III
Labels: 9 (ENVIRONM.)
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

NOM-002-SCT
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Caspofungin)
SAFETY DATA SHEET

Caspofungin Formulation

Class: 9
Packing group: III
Labels: 9

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.

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: Not applicable

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

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value
NOM-010-STPS-2014 / VLE-CT: Short term exposure limit value

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 Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 23.03.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8