## SECTION 1. IDENTIFICATION

<table>
<thead>
<tr>
<th>Product name</th>
<th>Caspofungin Formulation</th>
</tr>
</thead>
</table>

### Manufacturer or supplier's details

<table>
<thead>
<tr>
<th>Company name of supplier</th>
<th>Merck &amp; Co., Inc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>126 E. Lincoln Avenue</td>
</tr>
<tr>
<td></td>
<td>Rahway, New Jersey U.S.A. 07065</td>
</tr>
<tr>
<td>Telephone</td>
<td>908-740-4000</td>
</tr>
<tr>
<td>Emergency telephone</td>
<td>1-908-423-6000</td>
</tr>
<tr>
<td>E-mail address</td>
<td><a href="mailto:EHSDATASTEWARD@merck.com">EHSDATASTEWARD@merck.com</a></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Recommended use</th>
<th>Pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restrictions on use</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

## SECTION 2. HAZARDS IDENTIFICATION

### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Hazard Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combustible dust</td>
</tr>
<tr>
<td>Serious eye damage</td>
</tr>
</tbody>
</table>

### Effects on or via lactation

### GHS label elements

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
</tr>
</thead>
</table>

### Signal Word

<table>
<thead>
<tr>
<th>Signal Word</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danger</td>
</tr>
</tbody>
</table>

### Hazard Statements

If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

- **H318** Causes serious eye damage.
- **H362** May cause harm to breast-fed children.

### Precautionary Statements

**Prevention:**

- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P263 Avoid contact during pregnancy and while nursing.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear eye protection and face protection.

**Response:**

- P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present

<table>
<thead>
<tr>
<th>Date of last issue: 10/01/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of first issue: 10/21/2014</td>
</tr>
</tbody>
</table>
and easy to do. Continue rinsing. Immediately call a POISON CENTER.
P308 + P313 IF exposed or concerned: Get medical attention.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>Concentration (% w/w)</td>
</tr>
<tr>
<td>Caspofungin</td>
<td>47.1</td>
</tr>
<tr>
<td>Sucrose</td>
<td>30.3</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>1.5</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: 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. Get medical attention immediately.
If swallowed: Get medical attention.

Most important symptoms and effects, both acute and delayed:
- 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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- 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 prod-: 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 (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.

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 Advice on safe handling:
Use only with adequate ventilation.
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.

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**

<table>
<thead>
<tr>
<th>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (total dust)</td>
</tr>
<tr>
<td></td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (total dust)</td>
</tr>
<tr>
<td></td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
</tr>
<tr>
<td></td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>15 Million particles per cubic foot</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
</tr>
<tr>
<td></td>
<td>Basis: OSHA Z-3</td>
</tr>
</tbody>
</table>

**Dust, nuisance dust and particulates**

| 10 mg/m³ |
| Value type (Form of exposure): PEL (Total dust) |
| Basis: CAL PEL |

| 5 mg/m³ |
| Value type (Form of exposure): PEL (respirable dust fraction) |
| Basis: CAL PEL |

**Components**

<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>140 µg/m³ (OEB 2)</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></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>
Acetic acid 64-19-7  

<table>
<thead>
<tr>
<th>Compound</th>
<th>TWA</th>
<th>STEL</th>
<th>ACGIH</th>
<th>NIOSH REL</th>
<th>OSHA Z-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>10 ppm</td>
<td>15 ppm</td>
<td>STEL</td>
<td>25 mg/m³</td>
<td>TWA</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**

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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).

**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.
### SECTION 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>Color</td>
<td>off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor 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 range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
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
SAFETY DATA SHEET
Caspofungin Formulation

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
IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May cause harm to breast-fed children.

Components:

**Caspofungin:**

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

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Intravenous injection</td>
<td></td>
</tr>
<tr>
<td>General Toxicity Maternal: LOAEL: 5 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Embryo-fetal toxicity: NOAEL F1: 2 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Symptoms: Abnormalities of the musculoskeletal system.</td>
<td></td>
</tr>
<tr>
<td>Result: Embryotoxic effects and adverse effects on the offspring were detected.</td>
<td></td>
</tr>
</tbody>
</table>

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:**

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**STOT-single exposure**
Not classified based on available information.
STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Caspofungin:

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>27 Weeks</td>
</tr>
<tr>
<td>Number of exposures</td>
<td>daily</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1.8 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1.8 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>27 Weeks</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Swelling of tissue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>5 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Weeks</td>
</tr>
<tr>
<td>Number of exposures</td>
<td>daily</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Swelling of tissue</td>
</tr>
</tbody>
</table>

Acetic acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>290 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>8 Weeks</td>
</tr>
</tbody>
</table>

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

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

Toxicity to microorganisms: NOEC (Pseudomonas putid): 1,150 mg/l Exposure time: 16 h
Persistence and degradability

Components:

Caspofungin:
- 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. Do not dispose of waste into sewer.
- 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
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Domestic regulation

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

49 CFR
UN/ID/NA number: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Caspofungin)
Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (Caspofungin)
Remarks: Above applies only to containers over 119 gallons or 450 liters.
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Reproductive toxicity
- Serious eye damage or eye irritation

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Caspofungin 179463-17-3
- Sucrose 57-50-1
- D-mannitol 69-65-8
- Acetic acid 64-19-7

California List of Hazardous Substances
- Acetic acid 64-19-7

California Permissible Exposure Limits for Chemical Contaminants
- Sucrose 57-50-1
- Acetic acid 64-19-7

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Caspofungin Formulation

NFPA 704:

Flammability

Health

Instability

Special hazard

HMIS® IV:

HEALTH / 4

FLAMMABILITY 3

PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "∗" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
CAL PEL / PEL : Permissible exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; BC - 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 Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemi-

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8