SAFETY DATA SHEET
Tedizolid Solid Formulation

SECTION 1. IDENTIFICATION

Product name : Tedizolid Solid Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
          Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow, Blood, Gastrointestinal tract)

GHS label elements
Hazard pictograms : ⱳarahway

Signal Word : Warning
Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Bone marrow, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

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

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Tedizolid Phosphate</td>
<td>856867-55-5</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>19.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>1</td>
<td></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.

In case of eye contact:
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

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:
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.

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 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
Nitrogen oxides (NOx)
Metal 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.
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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.
Avoid contact with 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
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 labeled containers.
Store locked up.
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>Component</th>
<th>Value type (Form of exposure)</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inert or nuisance dust</td>
<td>50 Million particles per cubic foot</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>15 mg/m³</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td>Dust, nuisance dust and particulates</td>
<td>15 Million particles per cubic foot</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): TWA (respirable fraction)</td>
<td>Basis: OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>CAL PEL</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): PEL (Total dust)</td>
<td>Basis: CAL PEL</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
<td>CAL PEL</td>
</tr>
<tr>
<td></td>
<td>Value type (Form of exposure): PEL (respirable dust fraction)</td>
<td>Basis: CAL PEL</td>
</tr>
</tbody>
</table>

Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible | Basis |
|------------|---------|-------------------------------|---------------------------------|-------|

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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:
Safety goggles

Skin and body protection: Select appropriate protective clothing based on chemical exposure.

<table>
<thead>
<tr>
<th>Material</th>
<th>Concentration</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedizolid Phosphate</td>
<td>400 µg/m³ (OEB 2)</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>10 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>10 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>3 mg/m³</td>
<td>TWA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material</th>
<th>Concentration</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>5 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>5 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>15 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>5 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>10 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>5 mg/m³</td>
<td>TWA</td>
</tr>
<tr>
<td>Cellulose</td>
<td>3 mg/m³</td>
<td>TWA</td>
</tr>
</tbody>
</table>
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>yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>odorless</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>
</tbody>
</table>
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Version 8.0  Revision Date: 04/04/2023  SDS Number: 657013-00019  Date of last issue: 10/01/2022  Date of first issue: 05/03/2016

Autoignition temperature : No data available
Decomposition temperature : No data available

Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
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.

Components:

Tedizolid Phosphate:
  Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
  LD50 (Mouse): > 2,000 mg/kg
  Acute toxicity (other routes of administration) : LD50 (Mouse): 256 - 274 mg/kg
  Application Route: Intravenous
  LD50 (Rat): 244 mg/kg
Application Route: Intravenous

LD50 (Dog): 200 mg/kg

Application Route: Intravenous

Cellulose:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Magnesium stearate:

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 423
  Assessment: The substance or mixture has no acute oral toxicity
  Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Magnesium stearate:

Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Magnesium stearate:

Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.
**Components:**

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germs cell mutagenicity**
Not classified based on available information.

**Components:**

**Tedizolid Phosphate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Result: positive</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: unscheduled DNA synthesis assay Species: Rat Result: negative</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity - Assessment:**
Weight of evidence does not support classification as a germ cell mutagen.

**Cellulose:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
</tbody>
</table>

| Genotoxicity in vivo  | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Ingestion Result: negative |

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

|                       | Test Type: Chromosome aberration test in vitro |

Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials  

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials  

Carcinogenicity  
Not classified based on available information.  

Components:  
Cellulose:  
| Species | Rat |  
| Application Route | Ingestion |  
| Exposure time | 72 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  
Suspected of damaging the unborn child.  

Components:  
Tedizolid Phosphate:  
Effects on fertility  
| Test Type: Fertility/early embryonic development  
SpecieS: Rat, female  
Application Route: Oral  
Fertility: NOAEL: 15 mg/kg body weight  
Result: No effects on fertility. |  
Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: NOAEL: 50 mg/kg body weight  
Result: No effects on fertility. |  

Effects on fetal development  
| Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 25 mg/kg body weight  
Result: Reduced fetal weight, Skeletal malformations. |  
Test Type: Embryo-fetal development  
Species: Rat |
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Application Route: Oral
Developmental Toxicity: LOAEL: 15 mg/kg body weight
Result: Reduced fetal weight, Skeletal malformations.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 2.5 mg/kg body weight
Result: Reduced fetal weight, Skeletal malformations.

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

Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Magnesium stearate:
Effects on fertility: Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Bone marrow, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

Components:

Tedizolid Phosphate:
Target Organs: Bone marrow, Blood, Gastrointestinal tract
Assessment: May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Tedizolid Phosphate:**

- **Species:** Rat, female
- **NOAEL:** 10 mg/kg
- **Application Route:** Oral
- **Exposure time:** 28 d
- **Target Organs:** Lymph nodes, thymus gland, Bone marrow

- **Species:** Rat, male
- **NOAEL:** 30 mg/kg
- **Application Route:** Oral
- **Exposure time:** 28 d
- **Target Organs:** Bone marrow, spleen, Lymph nodes, thymus gland

- **Species:** Rat, female
- **NOAEL:** 15 mg/kg
- **Application Route:** Intravenous
- **Exposure time:** 28 d
- **Target Organs:** Gastrointestinal tract

- **Species:** Rat, male
- **NOAEL:** 30 mg/kg
- **Application Route:** Intravenous
- **Exposure time:** 28 d
- **Target Organs:** Gastrointestinal tract

- **Species:** Rat
- **NOAEL:** 2 mg/kg
- **LOAEL:** 5 mg/kg
- **Application Route:** Oral
- **Exposure time:** 6 Months
- **Symptoms:** Vomiting

**Cellulose:**

- **Species:** Rat
- **NOAEL:** >= 9,000 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**Magnesium stearate:**

- **Species:** Rat
- **NOAEL:** > 100 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Remarks:** Based on data from similar materials
Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Tedizolid Phosphate:
| Inhalation | Symptoms: Nausea, Headache, Diarrhea, Vomiting, Dizziness |
| Ingestion  | Symptoms: Nausea, Headache, Diarrhea, Vomiting, Dizziness |

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Tedizolid Phosphate:
| Toxicity to algae/aquatic plants | EC50 (Anabaena flos-aquae): 0.313 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
|                                   | NOEC (Anabaena flos-aquae): 0.0632 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | NOEC (Pimephales promelas (fathead minnow)): 0.03175 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)): 0.6 mg/l Exposure time: 21 d |
| Toxicity to microorganisms | EC50: > 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
|                           | NOEC: 100 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |

Cellulose:
| Toxicity to fish | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials |

Magnesium stearate:
| Toxicity to fish | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials |
Toxicity to daphnia and other aquatic invertebrates:
- EL50 (Daphnia magna (Water flea)): > 1 mg/l
- Exposure time: 47 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants:
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility.

- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

Toxicity to microorganisms:
- EC10 (Pseudomonas putida): > 100 mg/l
- Exposure time: 16 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

Persistence and degradability

Components:

Tedizolid Phosphate:
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 2 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301B
- Stability in water: Hydrolysis: 0 % (5 d)

Cellulose:
- Biodegradability: Result: Readily biodegradable.

Magnesium stearate:
- Biodegradability: Result: Not biodegradable
  - Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Tedizolid Phosphate:
- Partition coefficient: n-octanol/"water": log Pow: 1.3
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Tedizolid Solid Formulation

Octanol/water

**Magnesium stearate:** Partition coefficient: n-octanol/water : \( \log \text{Pow} > 4 \)

Mobility in soil

**Components:**

**Tedizolid Phosphate:** Distribution among environmental compartments : \( \log K_{oc} = 2.6 \)

**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. (Tedizolid Phosphate)
- Class : 9
- Packing group : III
- Labels : 9

**IATA-DGR**
- UN/ID No. : UN 3077
- Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Tedizolid Phosphate)
- Class : 9
- Packing group : III
- Labels : Miscellaneous
- Packing instruction (cargo aircraft) : 956
- Packing instruction (passenger aircraft) : 956
- Environmentally hazardous : yes

**IMDG-Code**
- UN number : UN 3077
- Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
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Date of first issue: 05/03/2016

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

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

Domestic regulation
49 CFR
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Tedizolid Phosphate)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (Tedizolid Phosphate)
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
This material does not contain any components with a CERCLA 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
Specific target organ toxicity (single or repeated exposure)

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
Tedizolid Solid Formulation

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Tedizolid Phosphate 856867-55-5
Cellulose 9004-34-6
D-mannitol 69-65-8
Polyvinyl pyrrolidone 9003-39-8

**California List of Hazardous Substances**

Polyvinyl pyrrolidone 9003-39-8

**California Permissible Exposure Limits for Chemical Contaminants**

Cellulose 9004-34-6
Magnesium stearate 557-04-0

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**

**NFPA 704:**

- **Flammability:** 1
- **Health:** 0
- **Special hazard:** 0
- **Instability:** 0

**HMIS® IV:**

- **HEALTH:** *
- **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
Tedizolid Solid Formulation

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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
OSHA Z-1 / TWA : 8-hour time weighted average
OSHA Z-3 / TWA : 8-hour time weighted average

AIIIC - 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 Toxinant; 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; 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; IECS - 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 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; 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


Revision Date: 04/04/2023

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.
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.

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