SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Tedizolid Solid Formulation

Version: 1.11
Revision Date: 2021/08/27
SDS Number: 657001-00012
Date of last issue: 2020/10/10
Date of first issue: 2016/05/03

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Tedizolid Solid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road
         HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
</tbody>
</table>

Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification

Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure: Category 2
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements

Hazard pictograms:

Signal word: Warning

Hazard statements:
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or re-
peated exposure.
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.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
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.

### Physical and chemical hazards
Not classified based on available information.

### Health hazards
Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

### Environmental hazards
Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

### Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedizolid</td>
<td>856867-55-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</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: 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: Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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

6. ACCIDENTAL RELEASE MEASURES
Tedizolid Solid Formulation

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 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.

7. HANDLING AND STORAGE

Handling:
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.

Avoidance of contact:
Oxidizing agents

Storage:
Conditions for safe storage:
Keep in properly labelled 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.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Tedizolid Solid Formulation

Version 1.11 Revision Date: 2021/08/27 SDS Number: 657001-00012 Date of last issue: 2020/10/10 Date of first issue: 2016/05/03

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSO...
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: yellow
Odour: odourless
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: Not applicable
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
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, dynamic: No data available
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
Particle size: No data available

10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means.
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

Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Tedizolid:
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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Magnesium stearate:
   Test Type: Maximisation Test
   Exposure routes: Skin contact
   Species: Guinea pig
   Method: OECD Test Guideline 406
**SAFETY DATA SHEET**
according to GB/T 16483 and GB/T 17519

**Tedizolid Solid Formulation**

**Version** 1.11  
**Revision Date:** 2021/08/27  
**SDS Number:** 657001-00012  
**Date of last issue:** 2020/10/10  
**Date of first issue:** 2016/05/03

---

**Result**  
- **Germ cell mutagenicity**  
  Not classified based on available information.

**Remarks**  
- Based on data from similar materials

**Components:**

**Tedizolid:**

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative

  Test Type: Chromosome aberration test in vitro  
  Result: positive

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
  Species: Mouse  
  Result: negative

  Test Type: unscheduled DNA synthesis assay  
  Species: Rat  
  Result: negative

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

**Cellulose:**

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative

  Test Type: In vitro mammalian cell gene mutation test  
  Result: negative

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

**Magnesium stearate:**

**Genotoxicity in vitro**
- Test Type: In vitro mammalian cell gene mutation test  
  Result: negative  
  Remarks: Based on data from similar materials

  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
Carcinogenicity
Not classified based on available information.

**Components:**

**Cellulose:**
- Species: Rat
- Application Route: Ingestion
- Exposure time: 72 weeks
- Result: negative

**Reproductive toxicity**
Suspected of damaging the unborn child.

**Components:**

**Tedizolid:**
- 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 foetal development:
  - Test Type: Embryo-foetal development
  - Species: Mouse
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 25 mg/kg body weight
  - Result: Reduced foetal weight, Skeletal malformations

  - Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 15 mg/kg body weight
  - Result: Reduced foetal weight, Skeletal malformations

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

**Remarks:** Based on data from similar materials

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

Effects on foetal 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 foetal development:
Test Type: Embryo-foetal 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 through prolonged or repeated exposure.

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

Repeated dose toxicity

Components:

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

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

**Species**: Dog  
**NOAEL**: 400 mg/kg  
**Application Route**: Oral  
**Exposure time**: 28 d  
**Symptoms**: Vomiting

**Cellulose**:

**Species**: Rat  
**NOAEL**: $\geq 9,000$ 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**:

**Inhalation**: Symptoms: Nausea, Headache, Diarrhoea, Vomiting, Dizziness  
**Ingestion**: Symptoms: Nausea, Headache, Diarrhoea, Vomiting, Dizziness
## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

**Tedizolid:**
- **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

**M-Factor (Acute aquatic toxicity):** 1

**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

**M-Factor (Chronic aquatic toxicity):** 1

**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:
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:
Partition coefficient: n-octanol/water: log Pow: 1.3

Magnesium stearate:
Partition coefficient: n-octanol/water: log Pow: > 4
Tedizolid Solid Formulation

Components:
Tedizolid:
Distribution among environmental compartments: \( \log \text{Koc}: 2.6 \)

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. (Tedizolid)
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)
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. (Tedizolid)
Class: 9
Packing group: III
Labels: 9
Tedizolid Solid Formulation

**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.

**National Regulations**

**GB 6944/12268**
**UN number:** UN 3077  
**Proper shipping name:** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tedizolid)

**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.

**15. REGULATORY INFORMATION**

**National regulatory information**

**Law on the Prevention and Control of Occupational Diseases**

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**
Sources of key data used to compile the Safety Data Sheet:

**Date format:** yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH:** USA. ACGIH Threshold Limit Values (TLV)
- **CN OEL:** Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
- **ACGIH / TWA:** 8-hour, time-weighted average
- **CN OEL / PC-TWA:** Permissible concentration - time weighted average
SAFETY DATA SHEET  
according to GB/T 16483 and GB/T 17519

Tedizolid Solid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.11</td>
<td>2021/08/27</td>
<td>657001-00012</td>
<td>2020/10/10</td>
<td>2016/05/03</td>
</tr>
</tbody>
</table>

Disclaimer
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.

CN / EN