SAFETY DATA SHEET
Tedizolid Injection Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Tedizolid Injection Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Bone marrow, Blood, Gastrointestinal tract)
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 (Bone marrow, Blood, Gastrointestinal tract) through prolonged or repeated 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/ fume/ gas/ mist/ vapours/ spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ 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.

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>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedizolid</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedizolid</td>
<td>856867-55-5</td>
<td>&gt;= 60 -&lt;= 100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-
vice 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 : 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

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- Do not swallow.
- 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 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedizolid</td>
<td>856867-55-5</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Use feasible engineering controls to minimize exposure to compound.
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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: Particulates type

Hand protection Material: Chemical-resistant gloves
Eye protection

Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Work uniform or laboratory coat.

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.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

(lyophilised)

Colour

white to off-white

Odour

deoourless

Odour Threshold

No data available

pH

7.4 - 8.1

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
Relative 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, 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

Information on likely routes of exposure : 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
Skin corosion/irritation
Not classified based on available information.

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

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

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.

Carcinogenicity
Not classified based on available information.

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

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

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:

Target Organs:
- Bone marrow, Blood, Gastrointestinal tract

Assessment:
- May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Tedizolid:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rat, female</th>
<th>Rat, male</th>
<th>Rat, female</th>
<th>Rat, male</th>
<th>Rat</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>10 mg/kg</td>
<td>30 mg/kg</td>
<td>15 mg/kg</td>
<td>30 mg/kg</td>
<td>2 mg/kg</td>
<td>400 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td>Oral</td>
<td>Intravenous</td>
<td>Intravenous</td>
<td>Oral</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
<td>28 d</td>
<td>28 d</td>
<td>28 d</td>
<td>6 Months</td>
<td>28 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Bone marrow, thymus gland, spleen, Lymph nodes</td>
<td>Bone marrow, Lymph nodes, spleen, thymus gland</td>
<td>Gastrointestinal tract</td>
<td>Gastrointestinal tract</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

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)

Bioaccumulative potential

**Components:**

**Tedizolid:**
## Mobility in soil

**Components:**

Tedizolid:
- Distribution among environmental compartments: log 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
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.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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: Internal technical data, data from raw material SDSs, OECD
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.

ID / EN