TEDIZOLID INJECTION FORMULATION

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Tedizolid Injection 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

Appearance: (lyophilised)
Colour: white to off-white
Odour: odourless

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/ fume/ gas/ mist/ vapours/ spray.
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 re-
peated 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

Substance / Mixture : Mixture

Components

<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;= 50 -&lt; 70</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.
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<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>1.9</td>
<td>09/13/2019</td>
<td>657042-00010</td>
<td>2019/04/24</td>
<td>2016/05/02</td>
</tr>
</tbody>
</table>

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

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 equip-
Tedizolid Injection Formulation

Emergency procedures

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 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

Packaging material:
Unsuitable material: None known.
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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
  - Eye/face 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.

Hand protection
- Material: Chemical-resistant gloves

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: odourless
- Odour Threshold: No data available
- pH: 7.4 - 8.1
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<table>
<thead>
<tr>
<th>Melting point/freezing point</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<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>No data available</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>No data available</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</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>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

| Reactivity | Not classified as a reactivity hazard. |
| Chemical stability | Stable under normal conditions. |
Tedizolid Injection Formulation

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

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

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

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
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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.

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
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IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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 mate-
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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