Tedizolid Solid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Tedizolid Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              Shotton Lane
              NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.
   Specific target organ toxicity - repeated exposure, Category 2 : H400: Very toxic to aquatic life.
   Short-term (acute) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.
   Long-term (chronic) aquatic hazard, Category 1 :

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Warning
   Hazard statements : H361d Suspected of damaging the unborn child. H373 May cause damage to organs through prolonged or repeated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements  
Prevention:  
P201  Obtain special instructions before use. 
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. 

Hazardous components which must be listed on the label: 
Tedizolid 

2.3 Other hazards  
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. 

SECTION 3: Composition/information on ingredients 

3.2 Mixtures  


For explanation of abbreviations see section 16. 

SECTION 4: First aid measures 

4.1 Description of 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.
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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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.
Tedizolid Solid Formulation

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NOx), Metal oxides
Tedizolid Solid Formulation

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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers
Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage
Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s)
No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

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

8.2 Exposure controls

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**

**Eye protection**
- Wear the following personal protective equipment:
  - Safety goggles
  - Equipment should conform to NS EN 166

**Hand protection**
- Material: Chemical-resistant gloves
- Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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.

**Skin and body protection**
- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
- Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**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 (P)

### SECTION 9: Physical and chemical properties

**9.1 Information on basic 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.
- **Upper explosion limit / Upper flammability limit**: No data available
Tedizolid Solid Formulation

9.2 Other information

Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Tedizolid Solid Formulation

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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

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
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Tedizolid Solid Formulation

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
- **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

**SECTION 12: Ecological information**

12.1 Toxicity

**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 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

Toxicity to fish (Chronic toxicity): NOEC: 0.03175 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.6 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic): 1
Tedizolid Solid Formulation

12.2 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)

12.3 Bioaccumulative potential

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

12.4 Mobility in soil

Components:
Tedizolid:
Distribution among environmental compartments: log Koc: 2.6

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
ADN: UN 3077
ADR: UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

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14.3 Transport hazard class(es)

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14.4 Packing group

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Tedizolid Solid Formulation

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that de- : Not applicable
Tedizolid Solid Formulation

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H361d  : Suspected of damaging the unborn child.
H373   : May cause damage to organs through prolonged or repeated exposure.
H400   : Very toxic to aquatic life.
H410   : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada-
Further information

Classification of the mixture:
Repr. 2 H361d Calculation method
STOT RE 2 H373 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

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.

NO / EN