

## Tedizolid Injection Formulation

Version 1.3      Revision Date: 05/02/2017      SDS Number: 657054-00004      Date of last issue: 11/08/2016  
Date of first issue: 05/02/2016

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### SECTION 1. IDENTIFICATION

Product name : Tedizolid Injection Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685  
Telephone : 908-740-4000  
Telefax : 908-735-1496  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - repeated exposure : Category 2

#### GHS label elements

Hazard pictograms :



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 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

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and understood.  
 P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ 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

Substance / Mixture : Mixture

**Hazardous ingredients**

| Chemical name | CAS-No.     | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Tedizolid     | 856867-55-5 | >= 50 - < 70          |

### 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 : Contact with dust can cause mechanical irritation or drying of

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and effects, both acute and delayed

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.

Notes to physician : Treat symptomatically and supportively.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### SECTION 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

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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.

### SECTION 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.  
 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

| Ingredients | CAS-No.     | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-------------|-------------|-------------------------------|--|-------|
| Tedizolid   | 856867-55-5 | TWA                           | 100 µg/m <sup>3</sup> (OEB 2)                  | Merck |

- Engineering measures** : Use feasible engineering controls to minimize exposure to compound.  
 All engineering controls should be implemented by facility

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design and operated in accordance with GMP principles to protect products, workers, and the environment.

### 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
- 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 : Ensure that eye flushing systems and safety showers are located 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : (lyophilized)
- Color : white to off-white
- Odor : odorless
- Odor Threshold : No data available
- pH : 7.4 - 8.1
- Melting point/freezing point : No data available

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|  |   |  |
|--|---|--|
| 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  |
| Vapor pressure                                   | : | No data available  |
| Relative vapor density                           | : | No data available  |
| Density  | : | No data available  |
| Solubility(ies)                                  | : |  |
| Water solubility                                 | : | No data available  |
| Partition coefficient: n-octanol/water           | : | No data available  |
| Autoignition 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  |

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**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | Not classified as a reactivity hazard.  |
| Chemical stability                 | : | Stable under normal conditions.   |
| Possibility of hazardous reactions | : | Dust can form an explosive mixture in air.<br>Can react with strong oxidizing agents. |

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Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Ingredients:****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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Ingredients:****Tedizolid:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

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|                                     |  |
|-------------------------------------|--|
|                                     | Result: negative   |
|                                     | : Test Type: Chromosome aberration test in vitro<br>Result: positive   |
| Genotoxicity in vivo                | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>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.

#### 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.

#### Ingredients:

#### Tedizolid:

|                                    |  |
|------------------------------------|--|
| Effects on fertility               | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 15 mg/kg body weight<br>Result: No effects on fertility.                                    |
| Effects on fetal development       | : Test Type: Embryo-fetal development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 5 mg/kg body weight<br>Symptoms: Skeletal malformations.<br>Result: Reduced fetal weight. |
|                                    | Test Type: Embryo-fetal development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 25 mg/kg body weight<br>Symptoms: Skeletal malformations.<br>Result: Reduced fetal weight.  |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on development, based on animal experiments.  |

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### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### Ingredients:

##### **Tedizolid:**

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

### Repeated dose toxicity

#### Ingredients:

##### **Tedizolid:**

Species: Rat  
NOAEL: 10 mg/kg  
LOAEL: 30 mg/kg  
Application Route: Oral  
Exposure time: 28 d  
Target Organs: Bone marrow, thymus, spleen, lymph node

Species: Rat  
NOAEL: 15 mg/kg  
LOAEL: 90 mg/kg  
Application Route: Intravenous  
Exposure time: 28 d  
Target Organs: Blood, Gastrointestinal tract

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Ingredients:

##### **Tedizolid:**

Inhalation : Symptoms: Nausea, Headache, Diarrhea, Vomiting, Dizziness

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Ingredients:

##### **Tedizolid:**

Toxicity to algae : 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

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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)): 0.03715 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****Ingredients:****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****Ingredients:****Tedizolid:**

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

**Mobility in soil****Ingredients:****Tedizolid:**

Distribution among environ- : log Koc: 2.6

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mental compartments

### Other adverse effects

No data available

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## SECTION 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.

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## SECTION 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

#### 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.

### Domestic regulation

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### 49 CFR

|                      |   |   |
|----------------------|---|---|
| UN/ID/NA number      | : | UN 3077   |
| Proper shipping name | : | Environmentally hazardous substance, solid, n.o.s. (Tedizolid)  |
| Class                | : | 9   |
| Packing group        | : | III   |
| Labels               | : | CLASS 9   |
| ERG Code             | : | 171   |
| Marine pollutant     | : | yes(Tedizolid)  |
| 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. |

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## SECTION 15. REGULATORY INFORMATION

### EPCRA - Emergency Planning and Community Right-to-Know

#### 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** : Fire Hazard  
Chronic Health Hazard

**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  | 856867-55-5 |
| D-mannitol | 69-65-8     |

#### California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

#### The ingredients of this product are reported in the following inventories:

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

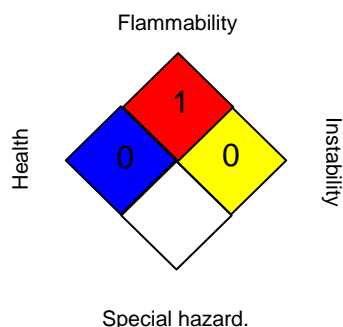
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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA:



##### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 2 |
| 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

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; 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; 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; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG -

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United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 05/02/2017

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 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.

US / Z8