

## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

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### SECTION 1. IDENTIFICATION

Product name : Tedizolid Injection Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 2 (Bone marrow, Blood, Gastrointestinal tract)  
- repeated exposure

#### 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.

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.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical attention.  
**Storage:**  
P405 Store locked up.

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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

### Disposal:

P501 Dispose of contents and 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.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Tedizolid Phosphate	No data available	856867-55-5	67

## 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 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.

## SECTION 5. FIRE-FIGHTING MEASURES

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
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---

- 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 : 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 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 (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 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.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

- Local/Total ventilation : Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Advice on safe handling : Use only with adequate ventilation.  
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 labeled containers.  
Store locked up.
- Materials to avoid : Store in accordance with the particular national regulations.  
Do not store with the following product types:  
Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Tedizolid Phosphate	856867-55-5	TWA	400 µg/m <sup>3</sup> (OEB 2)	Internal

- 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 : 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.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	657039-00019	Date of first issue: 05/02/2016

---

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.

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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
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	657039-00019	Date of first issue: 05/02/2016

---

Partition coefficient: n-octanol/water	:	Not applicable
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	:	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.

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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.

#### Components:

##### **Tedizolid Phosphate:**

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

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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	657039-00019	Date of first issue: 05/02/2016

---

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.

### **Components:**

#### **Tedizolid Phosphate:**

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 Phosphate:**

Effects on fertility : Test Type: Fertility/early embryonic development

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

---

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

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

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 2.5 mg/kg body weight  
Result: Reduced fetal 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 Phosphate:

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

### Repeated dose toxicity

### Components:

#### Tedizolid Phosphate:

Species : Rat, female  
NOAEL : 10 mg/kg  
Application Route : Oral



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

---

Exposure time : 28 d  
Target Organs : Lymph nodes, thymus gland, Bone marrow

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

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

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Tedizolid Phosphate:**

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae): 0.313 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

---

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

---

NOEC (Anabaena flos-aquae): 0.0632 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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 Phosphate:**

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 Phosphate:**

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

### Mobility in soil

#### Components:

##### **Tedizolid Phosphate:**

Distribution among environmental compartments : log Koc: 2.6

### Other adverse effects

No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 657039-00019      Date of last issue: 04/04/2023  
Date of first issue: 05/02/2016

---

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
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 Phosphate)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

##### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Tedizolid Phosphate)

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 Phosphate)

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

##### TDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	657039-00019	Date of first issue: 05/02/2016

N.O.S.  
(Tedizolid Phosphate)

Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Tedizolid Phosphate)

### 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.

## SECTION 15. REGULATORY INFORMATION

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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,

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Tedizolid Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
5.1	09/30/2023	657039-00019	Date of first issue: 05/02/2016

---

Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; 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

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 : 09/30/2023  
Date format : mm/dd/yyyy

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.

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