

# **Tedizolid Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 8.0 2024/09/28 657048-00023 Date of first issue: 2016/05/02

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Tedizolid Injection Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure

Category 2 (Bone marrow, Blood, Gastrointestinal tract)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Bone marrow, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.



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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.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

Important symptoms and outlines of the emergency assumed

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, han-

dling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name       | CAS-No.     | Concentration (% w/w) | ENCS No. |
|---------------------|-------------|-----------------------|----------|
| Tedizolid Phosphate | 856867-55-5 | >= 60 - < 70          | -        |
|                     |             |                       |          |

#### 4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention.



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Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact If in eves, 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. Suspected of damaging the unborn child.

Most important symptoms

and effects, both acute and

delayed

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. 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).

Treat symptomatically and supportively. Notes to physician

#### 5. FIREFIGHTING MEASURES

Protection of first-aiders

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

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 prod- :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

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, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).



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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 con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

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 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 as-

sessment

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 Hygiene measures

Oxidizing agents

: 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,



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industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

**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.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

| Components          | CAS-No.     | Value type<br>(Form of<br>exposure) | Control parameters / Concentration standard / Permissible concentration | Basis    |
|---------------------|-------------|-------------------------------------|---|----------|
| Tedizolid Phosphate | 856867-55-5 | TWA                                 | 400 μg/m3 (OEB<br>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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Particulates type

Hand protection

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : (lyophilised)

Colour : white to off-white



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Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling point and boiling range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit No data available

Flash point Not applicable

Decomposition temperature No data available

7.4 - 8.1pΗ

Evaporation rate Not applicable

No data available Auto-ignition temperature

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure Not applicable

Density and / or relative density

Relative density No data available

No data available Density

Relative vapour density Not applicable

Explosive properties Not explosive



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Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

# 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact

#### **Acute toxicity**

Not classified based on available information.

### **Components:**

#### **Tedizolid 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

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.



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### 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 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

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



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Fertility: NOAEL: 50 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

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 - As-

sessment

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
Exposure time : 28 d

Target Organs : Lymph nodes, thymus gland, Bone marrow

Species : Rat, male NOAEL : 30 mg/kg Application Route : Oral



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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, Diarrhoea, Vomiting, Dizzi-

ness

Ingestion : Symptoms: Nausea, Headache, Diarrhoea, Vomiting, Dizzi-

ness

### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### **Components:**

# **Tedizolid Phosphate:**

Toxicity to algae/aquatic : EC50 (Anabaena flos-aquae): 0.313 mg/l

plants Exposure time: 72 h

Method: OECD Test Guideline 201



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NOEC (Anabaena flos-aquae): 0.0632 mg/l

NOEC (Pimephales promelas (fathead minnow)): 0.03175

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

Toxicity to fish (Chronic tox-

icity)

mg/l Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity) M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

Exposure time: 21 d

NOEC (Daphnia magna (Water flea)): 0.6 mg/l

: 1

: 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

Hydrolysis: 0 %(5 d) Stability in water

Bioaccumulative potential

**Components:** 

**Tedizolid Phosphate:** 

Partition coefficient: n-

: log Pow: 1.3

octanol/water Mobility in soil

**Components:** 

**Tedizolid Phosphate:** 



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Distribution among environ-

mental compartments

log Koc: 2.6

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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 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)

Packing instruction (passen-

956

956

ger aircraft)

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



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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**

Refer to section 15 for specific national regulation.

### 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.

ERG Code : 171

### 15. REGULATORY INFORMATION

### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

### **Harmful Substances Required Permission for Manufacture**

Not applicable

### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

### **Substances Subject to be Notified Names**

Not applicable

### **Substances Subject to be Indicated Names**

Not applicable

### Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable



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Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning** 

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

**High Pressure Gas Safety Act** 

Not applicable

**Explosive Control Law** 

Not applicable

**Vessel Safety Law** 

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law** 

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

The components of this product are reported in the following inventories:



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AICS : not determined

DSL : not determined

IECSC : not determined

### **16. OTHER INFORMATION**

### **Further information**

Sources of key data used to compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

Date format : yyyy/mm/dd

#### 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, 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



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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.

JP / EN