

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ceftiofur Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 07/06/2024
5.0	09/28/2024	7674010-00014	Date of first issue: 12/15/2020

### SECTION 1. IDENTIFICATION

Product name : Ceftiofur 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 : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

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

Respiratory sensitization : Category 1  
Skin sensitization : Sub-category 1B  
Specific target organ toxicity : Category 2  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms	:
Signal Word	: Danger
Hazard Statements	: H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H373 May cause damage to organs through prolonged or repeated exposure if swallowed.
Precautionary Statements	: <b>Prevention:</b> P260 Do not breathe mist or vapors. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves. P284 Wear respiratory protection.  <b>Response:</b> P302 + P352 IF ON SKIN: Wash with plenty of water.

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P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Ceftiofur	No data available	103980-44-5	$\geq 4.7619 - \leq 5.8824$
Benzyl alcohol	Benzenemethanol	100-51-6	$\geq 0.9524 - \leq 1.1765$
Silicon, amorphous	Silicon dioxide	112945-52-5	$\geq 0.9524 - \leq 1.1765$

## 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.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
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 : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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May cause damage to organs through prolonged or repeated exposure if swallowed.  
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

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

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.

### 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.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
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 : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate

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containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.

Clean up remaining materials from spill with suitable absorbent.

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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ceftiofur	103980-44-5	TWA	100 mcg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN, DSEN				
Silicon, amorphous	112945-52-5	TWAEV (respirable)	6 mg/m <sup>3</sup>	CA QC OEL

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II		dust)		
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**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

### 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** : Combined particulates and organic vapor type

**Hand protection** : Chemical-resistant gloves

**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** : 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.  
Contaminated work clothing should not be allowed out of the workplace.  
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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** : suspension

**Color** : white to off-white, cream

**Odor** : No data available

**Odor Threshold** : No data available

**pH** : No data available

**Melting point/freezing point** : No data available

**Initial boiling point and boiling range** : No data available

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Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
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
Relative density	:	No data available
Density	:	0.850 - 1.050 g/cm <sup>3</sup> No data available
Solubility(ies)		
Water solubility	:	No data available
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 characteristics		
Particle size	:	Not applicable

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.

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Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
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#### Components:

##### **Ceftiofur:**

Acute oral toxicity	:	LD50 (Rat): > 7,760 mg/kg
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##### **Benzyl alcohol:**

Acute oral toxicity	:	LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.4 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity

##### **Silicon, amorphous:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute inhalation toxicity	:	LC50 (Rat): > 2.08 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg Remarks: Based on data from similar materials

#### **Skin corrosion/irritation**

Not classified based on available information.

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### Components:

#### **Benzyl alcohol:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

#### **Silicon, amorphous:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation
Remarks	: Based on data from similar materials

### **Serious eye damage/eye irritation**

Not classified based on available information.

### Components:

#### **Benzyl alcohol:**

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days
Method	: OECD Test Guideline 405

#### **Silicon, amorphous:**

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405
Remarks	: Based on data from similar materials

### **Respiratory or skin sensitization**

#### **Skin sensitization**

May cause an allergic skin reaction.

#### **Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Components:

#### **Ceftiofur:**

Routes of exposure	: Inhalation
Result	: Sensitizer
Remarks	: May cause sensitization by inhalation.

#### **Benzyl alcohol:**

Test Type	: Human repeat insult patch test (HRIPT)
Routes of exposure	: Skin contact
Species	: Humans
Result	: positive

Assessment	: Probability or evidence of low to moderate skin sensitization
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II rate in humans

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Ceftiofur:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: In vitro mammalian cell gene mutation test Result: negative  Test Type: unscheduled DNA synthesis assay Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Rat Application Route: Intraperitoneal Result: negative

#### Benzyl alcohol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

#### Silicon, amorphous:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials
Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.

### Components:

#### Benzyl alcohol:

Species	: Mouse
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Application Route	: Ingestion
Exposure time	: 103 weeks
Method	: OECD Test Guideline 451
Result	: negative

### Silicon, amorphous:

Species	: Rat
Application Route	: Ingestion
Exposure time	: 103 weeks
Result	: negative
Remarks	: Based on data from similar materials

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Ceftiofur:

Effects on fertility	: Test Type: Fertility Application Route: Oral Fertility: NOAEL: 1,000 mg/kg body weight Result: No adverse effects.
Effects on fetal development	: Test Type: Development Application Route: Oral Developmental Toxicity: NOAEL: 1,000 mg/kg body weight Result: No adverse effects.

#### Benzyl alcohol:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on fetal development	: Test Type: Embryo-fetal development Species: Mouse Application Route: Ingestion Result: negative

#### Silicon, amorphous:

Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
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### STOT-single exposure

Not classified based on available information.

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### STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure if swallowed.

#### Components:

##### Ceftiofur:

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

### Repeated dose toxicity

#### Components:

##### Ceftiofur:

Species	: Rat
NOAEL	: 30 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: Gastrointestinal tract
Symptoms	: Gastrointestinal disturbance
Remarks	: May cause damage to organs.

Species	: Dog
NOAEL	: 30 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Target Organs	: Blood, Central nervous system
Remarks	: May cause damage to organs.

##### Benzyl alcohol:

Species	: Rat
NOAEL	: 1.072 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 28 Days
Method	: OECD Test Guideline 412

##### Silicon, amorphous:

Species	: Rat
NOAEL	: 1.3 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 13 Weeks
Remarks	: Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Ceftiofur:

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General Information	: Repeated contact may cause allergic reactions in very susceptible persons.
Inhalation	: Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis, Headache, Dizziness, dry mouth, Fatigue, constipation, colitis

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Benzyl alcohol:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

##### **Silicon, amorphous:**

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 24 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials  NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l Exposure time: 72 h

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Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

##### Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

### Bioaccumulative potential

#### Components:

##### Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

### Mobility in soil

No data available

### Other adverse effects

No data available

## 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.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

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### Special precautions for user

Not applicable

## SECTION 15. REGULATORY INFORMATION

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

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

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
CA QC OEL / TWAEV	:	Time-weighted average exposure value

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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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 : 09/28/2024  
Date format : mm/dd/yyyy

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.

CA / Z8