

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Ceftolozane / Tazobactam Injection Formulation

Version 5.1 Revision Date: 09/30/2023 SDS Number: 438895-00020 Date of last issue: 04/04/2023
Date of first issue: 01/06/2016

SECTION 1. IDENTIFICATION

Product name : Ceftolozane / Tazobactam 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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Respiratory sensitization : Sub-category 1B
Specific target organ toxicity : Category 2 (Kidney, Liver)
- repeated exposure

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373 May cause damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust.
P284 Wear respiratory protection.
Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.

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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)
Ceftolozane	No data available	689293-68-3	$\geq 30 - < 60$ *
Tazobactam	No data available	89786-04-9	$\geq 10 - < 30$ *

* Actual concentration or concentration range is withheld as a trade secret

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.
Get medical attention if symptoms occur.
- 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 if symptoms occur.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause damage to organs through prolonged or repeated exposure.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
Contact with dust can cause mechanical irritation or drying of the skin.

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Protection of first-aiders : 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).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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 products : Carbon oxides
Metal oxides
Chlorine compounds
Nitrogen oxides (NO_x)

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.
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 : Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.
Add excess liquid to allow the material to enter into solution.
Soak up with inert absorbent material.
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

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released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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. 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. Keep tightly closed. 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ceftolozane	689293-68-3	TWA	1000 µg/m ³ (OEB 1)	Internal
Further information: DSEN, RSEN				

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		Wipe limit	100 µg/100 cm ²	Internal
Tazobactam	89786-04-9	TWA	250 µg/m ³ (OEB 2)	Internal
Further information: RSEN				
		Wipe limit	100 µg/100 cm 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

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.
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 : powder

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

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
Relative 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

SECTION 10. STABILITY AND REACTIVITY

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

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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.

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

Components:

Ceftolozane:

Acute toxicity (other routes of administration) : LD50 (Rat): > 2,000 mg/kg
Application Route: Intravenous

LD50 (Mouse): > 1,500 mg/kg
Application Route: Intravenous

LD50 (Dog): > 2,000 mg/kg
Application Route: Intravenous

Tazobactam:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): > 5,000 mg/kg
Application Route: Intravenous

LD50 (Mouse): > 5,000 mg/kg
Application Route: Intravenous

LD50 (Dog): > 5,000 mg/kg
Application Route: Intravenous

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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

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

Components:

Ceftolozane:

Test Type : Maximization Test
Species : Guinea pig
Result : Sensitizer

Tazobactam:

Result : Sensitizer

Germ cell mutagenicity

Not classified based on available information.

Components:

Ceftolozane:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: positive

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Mouse
Result: negative

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Tazobactam:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: positive
- Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster fibroblasts
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
- Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Ceftolozane:

- Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intravenous injection
Fertility: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility.
- Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 2,000 mg/kg body weight
Remarks: No significant adverse effects were reported
- Test Type: Embryo-fetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Remarks: No significant adverse effects were reported

Tazobactam:

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Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intraperitoneal injection
Fertility: NOAEL: 640 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal injection
Developmental Toxicity: NOAEL: 40 mg/kg body weight
Result: Effects on early embryonic development.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight
Result: No effects on fetal development.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Components:

Ceftolozane:

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

Tazobactam:

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

Repeated dose toxicity

Components:

Ceftolozane:

Species : Rat
NOAEL : 1,000 mg/kg
Application Route : Intravenous
Exposure time : 28 days
Target Organs : Kidney
Symptoms : No adverse effects.

Species : Dog
LOAEL : 300 mg/kg
Exposure time : 28 days
Target Organs : Kidney

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Tazobactam:

Species : Rat
NOAEL : 40 mg/kg
Application Route : Intraperitoneal
Exposure time : 6 Months
Target Organs : Liver

Species : Dog
NOAEL : 40 mg/kg
LOAEL : 80 mg/kg
Application Route : Intraperitoneal
Exposure time : 6 Months
Target Organs : Liver

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ceftolozane:

Ingestion : Symptoms: Diarrhea, Fever, Headache, Nausea, Skin irritation, Gastrointestinal discomfort

Tazobactam:

Inhalation : Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ceftolozane:

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae): 0.0401 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.0018 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 10 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)): 9.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 560 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Tazobactam:

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae): 0.96 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.44 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 10.6 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)): 9.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Ceftolozane:

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301D

Tazobactam:

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301D

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Bioaccumulative potential

Components:

Ceftolozane:

Partition coefficient: n-octanol/water : log Pow: -0.21

Tazobactam:

Partition coefficient: n-octanol/water : log Pow: -0.63

Mobility in soil

Components:

Ceftolozane:

Distribution among environmental compartments : log Koc: 3.3
Method: OECD Test Guideline 106

Tazobactam:

Distribution among environmental compartments : log Koc: 0.87

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

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ceftolozane, Tazobactam)

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.

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(Ceftolozane, Tazobactam)
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.
(Ceftolozane, Tazobactam)

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, N.O.S.
(Ceftolozane, Tazobactam)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Ceftolozane, Tazobactam)

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

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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, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - 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/>

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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

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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