according to the OSHA Hazard Communication Standard



Ceftolozane / Tazobactam Injection Formulation

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SECTION 1. IDENTIFICATION

Product name Ceftolozane / Tazobactam Injection Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Respiratory sensitization Category 1

Specific target organ toxicity : Category 2 (Kidney, Liver)

repeated exposure

Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

GHS label elements

Hazard pictograms



Signal Word Danger

If small particles are generated during further processing, han-Hazard Statements

dling or by other means, may form combustible dust concentra-

tions in air.

H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

H373 May cause damage to organs (Kidney, Liver) through

prolonged or repeated exposure.

Precautionary Statements Prevention:

P260 Do not breathe dust.

according to the OSHA Hazard Communication Standard



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P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a doc-

tor.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Ceftolozane	689293-68-3*	>= 30 - <= 60	TSC
Tazobactam	89786-04-9*	>= 10 - <= 30	TSC

^{*} Indicates that the identifier is a CAS No.

TSC- the 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

: 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.

according to the OSHA Hazard Communication Standard



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Dust contact with the eyes can lead to mechanical irritation.

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

May cause damage to organs through prolonged or repeated

exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (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 prod-

ucts

Carbon oxides

Metal oxides

Chlorine compounds Nitrogen oxides (NOx)

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

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, protec- :

tive equipment and emer-

gency 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.

according to the OSHA Hazard Communication Standard



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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 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 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

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

according to the OSHA Hazard Communication Standard



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust 50 Million particles per cubic foot

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

15 mg/m³

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

5 mg/m³

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

15 Million particles per cubic foot

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

Dust, nuisance dust and par-

ticulates

10 mg/m³

Value type (Form of exposure): PEL (Total dust)

Basis: CAL PEL

5 mg/m³

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

Components	CAS-No.	Value type	Control parame-	Basis		
		(Form of	ters / Permissible			
		exposure)	concentration			
Ceftolozane	689293-68-3	TWA	1000 μg/m3 (OEB	Internal		
			1)			
	Further inform	Further information: DSEN, RSEN				
		Wipe limit	100 µg/100 cm ²	Internal		
Tazobactam	89786-04-9	TWA	250 µg/m3 (OEB	Internal		
			2)			
	Further inform	Further information: RSEN				
		Wipe limit	100 μg/100 cm2	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 : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where

concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

Follow OSHA respirator regulations (29 CFR 1910.134) and

according to the OSHA Hazard Communication Standard



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use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection

Hygiene measures

Work uniform or laboratory coat.

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

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

according to the OSHA Hazard Communication Standard



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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 characteristics

Particle size : No data available

SECTION 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,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

: Oxidizing agents

products

: No hazardous decomposition products are known.

according to the OSHA Hazard Communication Standard



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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.

Product:

: Acute toxicity estimate: > 5,000 mg/kg Acute oral toxicity

Method: Calculation method

Components:

Ceftolozane:

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

administration)

Application Route: Intravenous

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

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

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

LD50 (Dog): > 5,000 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.

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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

Tazobactam:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

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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.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

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

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Remarks: No significant adverse effects were reported

Tazobactam:

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

according to the OSHA Hazard Communication Standard



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

Tazobactam:

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

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 irrita-

tion, Gastrointestinal discomfort

Tazobactam:

Remarks: May cause allergy or asthma symptoms or breath-Inhalation

ing difficulties if inhaled.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ceftolozane:

Toxicity to algae/aquatic : EC50 (Anabaena flos-aquae): 0.0401 mg/l

Exposure time: 72 h plants

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 tox-

: NOEC (Pimephales promelas (fathead minnow)): 10 mg/l icity) Exposure time: 32 d

Method: OECD Test Guideline 210

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Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic 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: 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 tox-

icity)

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 (Chron-

ic 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.

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Method: OECD Test Guideline 301D

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 environ: log Koc: 3.3

mental compartments

Method: OECD Test Guideline 106

Tazobactam:

Distribution among environ-

mental compartments

log Koc: 0.87

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Empty containers should be taken to an approved waste Contaminated packaging

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

: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Ceftolozane, Tazobactam)

Class 9 Ш Packing group 9 Environmentally hazardous yes

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IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Ceftolozane, Tazobactam)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo :

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

956

(Ceftolozane, Tazobactam)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Ceftolozane, Tazobactam)

Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171

Marine pollutant : yes(Ceftolozane, Tazobactam)

Remarks : Above applies only to containers over 119 gallons or 450

liters.

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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.

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SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards

Combustible dust

Respiratory or skin sensitization

Specific target organ toxicity (single or repeated exposure)

SARA 313

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Ceftolozane689293-68-3L-Arginine hydrochloride1119-34-2Tazobactam89786-04-9Sodium chloride7647-14-5

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

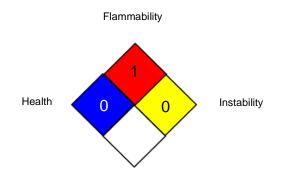
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NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

CAL PEL : California permissible exposure limits for chemical contami-

nants (Title 8, Article 107)

OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-

eral Dusts

CAL PEL / PEL : Permissible exposure limit
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-

according to the OSHA Hazard Communication Standard



Ceftolozane / Tazobactam Injection Formulation

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tative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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 Agen-

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

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

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