

Piperacillin and Tazobactam for Injection, USP, 2.25g, Sterile Powder; Piperacillin and Tazobactam for Injection, USP, 3.375g, Sterile Powder; Piperacillin and Tazobactam for Injection, USP, 4.5g, Sterile Powder; Piperacillin and Tazobactam for Injection, USP, 40.5g, Sterile Powder

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 02/24/2021

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Piperacillin and Tazobactam for Injection, USP, 2.25g, Sterile Powder; Piperacillin and Tazobactam for Injection, USP, 3.375g, Sterile Powder; Piperacillin and Tazobactam for Injection, USP, 4.5g, Sterile Powder; Piperacillin and Tazobactam for Injection, USP, 40.5g, Sterile Powder

CAS-No.: 157044-21-8

1.2. Intended Use of the Product

Pharmaceutical

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
Website: www.fresenius-kabi.com/us/

Manufacturer

Mitim S.r.l.
Via Gian Battista Cacciamali 36
Brescia 25125, Italy
General Phone Number: 030 349761

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Resp. Sens. 1 H334
Skin Sens. 1 H317
Comb. Dust

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



GHS08

Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: May form combustible dust concentrations in air.
H317 - May cause an allergic skin reaction.
H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US/CA)

: P261 - Avoid breathing dust.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.

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P284 - [In case of inadequate ventilation] wear respiratory protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Supplemental Information

: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Proper grounding procedures to avoid static electricity should be followed. Prevent dust accumulation (to minimize explosion hazard). Avoid generating dust.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

11% of the mixture consists of ingredient(s) of unknown acute toxicity (Oral)

100% of the mixture consists of ingredient(s) of unknown acute toxicity (Dermal)

100% of the mixture consists of ingredient(s) of unknown acute toxicity (Inhalation (Dust/Mist))

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino]phenylacetyl]amino]-3,3-dimethyl-7-oxo-, monosodium salt, [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]-	Piperacillin sodium / [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]-6-[[[(4-ethyl-2,3-dioxopiperazin-1-yl)carbonyl]amino]phenylacetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid / piperacillin sodium	(CAS-No.) 59703-84-3	89	Resp. Sens. 1, H334 Skin Sens. 1, H317 Comb. Dust
Tazobactam sodium salt	tazobactam sodium	(CAS-No.) 89785-84-2	11	Resp. Sens. 1, H334 Skin Sens. 1, H317 Comb. Dust

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

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Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization.

Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction. Dust may be harmful or cause irritation.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Sulfur oxides.

Other Information: Risk of dust explosion.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

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6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing dust. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong oxidizers. Aminoglycosides. Moisture.

Storage Temperature: 20 to 25 °C (68 to 77 °F) See USP Controlled Room Temperature

7.3. Specific End Use(s)

Pharmaceutical

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

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Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: White microcrystalline powder
Odor	: Odorless or weak characteristic odor
Odor Threshold	: Not available
pH	: 5 – 7
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: Not available
Relative Density	: Not available
Specific Gravity	: Not available
Solubility	: Water: Very soluble
Partition Coefficient: N-Octanol/Water	: 1.88
Viscosity	: Not available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).
- 10.5. Incompatible Materials:** Strong oxidizers. Aminoglycosides. Moisture.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified
Acute Toxicity (Dermal): Not classified
Acute Toxicity (Inhalation): Not classified
LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified
pH: 5 – 7
Eye Damage/Irritation: Not classified

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pH: 5 – 7

Respiratory or Skin Sensitization: May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction. Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None known.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino]phenylacetyl]amino]-3,3-dimethyl-7-oxo-, monosodium salt, [2S-[2.alpha.,5.alpha.,6.beta.(S*)]]- (59703-84-3)

LD50 Oral Rat	> 10 g/kg
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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.
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12.3. Bioaccumulative Potential

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Bioaccumulative Potential	Not established.
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12.4. Mobility in Soil Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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- 14.1. In Accordance with DOT** Not regulated for transport
- 14.2. In Accordance with IMDG** Not regulated for transport
- 14.3. In Accordance with IATA** Not regulated for transport
- 14.4. In Accordance with TDG** Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes

Health hazard - Respiratory or skin sensitization
Physical hazard - Combustible dust

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

15.3. Canadian Regulations

This product or its components are not listed on the Canadian Domestic Substances List (DSL) or the Non-Domestic Substances List (NDSL), or are not required to be disclosed.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest : 02/24/2021

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

Comb. Dust	Combustible Dust
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1
H317	May cause an allergic skin reaction
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)