

Section 1: IDENTIFICATION OF SUBSTANCE AND SOCIETY

1.1. Identification of the substance

Product form: Powder to mix with liquid and injected intravenously.

Product name: Piperacillin and Tazobactam for injection, USP.

Chemical name: Piperacillin: (2S, 5R, 6R)-6-[(R)-2-(4-ethyl-2,3-dioxo-1-piperazine-carboxamido)-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate ;

Tazobactam: (2S, 3S, 5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate-4,4-dioxide.

Synonym: PipTaz.

National Drug Code (NDC): 2.25G : 81284-151-00 ; 3.375 g : 81284-152-00 ; 4.5g : 81284-153-00 ; 13.5g : 81284-154-00 ; 40.5g : 81284-155-00.

Trade name: Not applicable.

Molecular formula: Piperacillin sodium: $C_{23}H_{26}N_5NaO_7S$; Tazobactam sodium $C_{10}H_{11}N_4NaO_5S$.

CAS No.: Piperacillin sodium: 59703-84-3; Tazobactam sodium: 89785-84-2.

EC No.: Not applicable.

REACH No.: Not applicable

1.2. Uses

Pharmaceutical. Treatment of bacterial infections.

1.3. Information about the security data sheet provider

Company	Supplier	Distributor
Provepharm SAS 22 Rue Marc Donadille 13013 Marseille, France Phones: 04 91 08 69 30 Website: www.provepharm.com Email: hse@provepharm.com	Recipharm MITIM S.r.l via Cacciamali 36/38 Brescia, Italy	Provepharm Inc. 100 Springhouse drive, Suite 105, Collegeville, PA 19426, USA Phone: +1 610 601 8600

1.4. Emergency telephone number:

CHEMTREC: 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or the mixture

Potential Acute Health Effects: May be harmful in case of skin contact (irritant), of eye contact (irritant), and inhalation.

Potential Chronic Health Effects: May cause allergic reactions in individuals with a history of penicillin hypersensitivity or a history to multiple allergens. The most common effects may include diarrhea, headache, constipation, nausea, insomnia, rash, vomiting, dyspepsia, pruritus, stool changes, fever, agitation, pain, moniliasis, hypertension, dizziness, abdominal pain, chest pain, edema, anxiety, rhinitis, and dyspnea.

Carcinogenic Effects: Long-term carcinogenicity studies in animals have not been conducted with piperacillin/tazobactam, piperacillin, or tazobactam. This material is not considered to be a carcinogen by IARC, NIP or OSHA.

Mutagenic Effects: Not available.

Teratogenic Effects: Animal studies have failed to reveal evidence of fetal toxicity or teratogenicity.

Developmental Toxicity: Classified development toxin (possible). The substance may be toxic to kidneys. Repeated or prolonged exposure to the substance can produce target organ damage.

Adverse effects: Not available

2.2. Label elements

Warning mention: Danger

Hazard statements:

H317 - May cause an allergic skin reaction.



H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.

P285 - In case of inadequate ventilation wear respiratory protection.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.

P321 - Specific treatment (see supplemental first aid instructions on this label).

P363 - Wash contaminated clothing before reuse.

2.3. Other hazards

An occupational exposure value has been established for one or more of the ingredients (see Section 8).

2.4. Unknown acute toxicity

Not applicable.

Section 3: COMPOSITION/INFORMATIONS ON THE SUBSTANCE

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	Weight	Classification
Piperacillin sodium	Cas-No.: 59703-84-3 Molecular Weight: 539.54 g/mole	2 - 4 g/vial	Resp. Sens. 1,H334 Skin Sens. 1,H317
Tazobactam sodium	Cas-No.: 89785-84-2 Molecular Weight: 322.28 g/mole	0.25 - 0.5 g/vial	Not applicable

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

After inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

After skin contact: In case of contact, immediately wash skin with plenty of water and soap for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

After eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

After ingestion: Do not induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

Notes to physician: See product package insert for complete information. Treat symptoms.

4.2. Most important symptoms and effects, both acute and delayed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Small fire: Use water spray, dry chemical, carbon dioxide or foam, as appropriate for surrounding fire and materials. Large fire: Use water spray, fog or foam, dry chemical or carbon dioxide. May use type ABC multi-purpose extinguisher.

Unsuitable extinguishing media: Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Fire or explosion hazard: None.

Flammability of the product: May combust at high temperatures.

Combustion Products: Decomposition products may include carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂), other noxious gases or vapors.

5.3. Advice for firefighters

Protective equipment & precautions for firefighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protecting clothing and equipment as described in section 8. Ventilate the area. Eliminate all ignition sources.

6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3. Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. A high efficiency vacuum may be used to collect spillage. Avoid breathing dust. Finish cleaning by spreading water and soap on the contaminated spill site.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. AVOID breathing dust. Finish cleaning by spreading water and soap on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container labelled appropriately for disposal.

For proper waste disposal, see section 13 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

As a general rule, when handling Piperacillin and Tazobactam for injection, USP, avoid inhalation, contact with eyes, skin and clothing. Avoid prolonged or repeat exposure. Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. Do Not ingest. Do Not breathe dust. Wear suitable protective clothing. Use only in accordance with directions.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Store at 68° to 77°F (20° to 25°C); excursions permitted between 59° and 86°F (15° and 30°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Keep away from strong oxidizing agents and bases.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limit: Not available.

8.2. Exposure controls

Appropriate engineering controls: Use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operation generates dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Hand protection: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations (in accordance with EN374, ASTM F1001 or international equivalent).

Eye protection: Wear safety glasses or goggles if eye contact is possible (in accordance with EN166, ANSI Z87.1 or international equivalent).

Skin and body protection: Wear suitable working clothes.

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter) (in accordance with EN140, EN143, ASTM F2704-10 or international equivalent).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Solid powder
Appearance:	No data available
Color:	White to off-white
Odor:	Odorless
Odor threshold:	No data available
pH:	5.0 – 7.0
Melting point:	311°F (155°C)
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Relative evaporation rate (butyl acetate=1):	No data available
Flammability (solid, gas):	No data available
Vapor pressure:	No data available
Relative vapor density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Very soluble in water
Partition coefficient n-octanol/water (Log Pow):	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosion limits:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

9.2. Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product is stable under normal conditions.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

Store away from strong oxidizers and strong bases.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

During thermal decomposition, it may emit irritating and/or toxic fumes of carbon dioxide, nitrogen oxides or sulfur oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity:

Piperacillin sodium:

LD50 (oral), rat:	>10 g/kg
LD50 (oral), mice:	>10 g/kg
LD50 (intravenous), rat:	2260 mg/kg
TDLo (intravenous), woman:	2180 mg/kg, 6 days
TDLo (intramuscular), woman:	960 mg/kg, 3 days
LD50 (intraperitoneal), mice:	9770 mg/kg
LD50 (subcutaneous), mice:	>10 g/kg
LD50 (intravenous), mice:	4900 mg/kg
LD50 (intravenous), dog:	>6 g/kg
LD50 (intravenous), monkey:	>4 g/kg

Tazobactam sodium:

LD50 (oral), mice:	>5,000 mg/kg
LD50 (oral), rat:	>5,000 mg/kg
LD50 (intravenous), mice:	>5,000 mg/kg
LD50 (intravenous), rat:	>5,000 mg/kg

Routes of exposure: Dermal contact, eye contact, inhalation, ingestion.

Carcinogenic/mutagenic/toxic effects for reproduction: Animal studies have failed to reveal evidence of fetal toxicity or teratogenicity. There are no controlled data in human pregnancies. However, Piperacillin is excreted into human milk in small amounts. Material crosses the placenta and is excreted in human milk. May be harmful to pregnant women and their babies. May be harmful to breastfed babies. There are no data on the excretion of Tazobactam into human milk.

Specific target organ toxicity – single exposure: Not available.

Specific target organ toxicity – repeated exposure: Not available.

Aspiration hazard: Not available.

Symptoms short term: Hazardous in cases of inhalation. Hazardous in case of skin contact (irritant). Symptoms such as skin rash, diarrhea, nausea, vomiting or rash are commonly observed.



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Symptoms long term: Exposure may result in blood and lymphatic system disorder, leading to infections. May cause damage to the following organs: Kidneys.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Microorganism: Minimum inhibitory concentration (MIC) >1000 mg/l for 3 test species.

Pseudomonas MIC=250 mg/l Daphnia: LC50 / 48h/daphnia >8.5 mg/l NOEC=8.5 mg/l.

12.2. Persistence and degradability

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. Stable at pH 7 and below. At pH 9, half-life = 29h. The product itself and its products of degradation are not toxic.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Other adverse effects

Do not discharge into the drains/surface waters/ground water.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste classification: Non-hazardous.

Advice on disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste disposal number of waste from residues/unused products : Dispose of waste in accordance with federal, state and local environment control regulations.

Contaminated packaging: Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: TRANSPORT INFORMATION

Department of Transportation (DOT) Classification:

UN Number: Not regulated.

UN Shipping name: Not available.

Transport hazard class: Not available.

Packing Group: Not available.

Environmental hazard: Not available.

Transport in bulk: Not available.

Special precautions needed with transport: Not available.

SECTION 15: REGULATORY INFORMATION

15.1. EU Federal and State Regulations

U.S. Regulations:

TSCA - No CERCLA - Not on this list

SARA 302 – Not on this list

SARA 311 - Not on this list

SARA 312 – Not on this list



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SARA 313 – Not on this list
OSHA Substance Specific – No

15.2. Other classifications

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R36/38-Irritating to eyes and skin. R61- may cause harm to the unborn child.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

US OSHA Classification: Possible Sensitizer, Target Organ Toxin, Possible Irritant

SECTION 16: OTHER INFORMATION

None.