

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Piperacillin and Tazobactam for Injection**
Manufacturer Name: Haupt Pharma Latina S.r.L.
Address: S.S.156 Km 47,600 – 04100 Borgo San Michele (Latina)
 Italy
General Phone Number: (847) 550-2300
General Fax Number: +39 0773 250920
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
Technical Product Information: +39 0773 4251
Distributor Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Health Issues Information: (800) 551-7176
SDS Creation Date: February 04, 2019
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SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: WARNING!

GHS Class: Not applicable.

Hazard Statements: Not applicable.

Precautionary Statements: Not applicable.

Emergency Overview: Non hazardous (except to people allergic to penicillins)

Route of Exposure: Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation.

Chronic Health Effects:

Repeat-dose studies up to 6 months in duration employing parenteral routes of exposure (iv and ip) in the rat and dog have established the liver (altered glycogen disposition) and cecum (enlargement) as target organs of toxicity for pip/tazo. (this effect on glycogen distribution is a well-known effect of b-lactamase inhibitors, and the cecal effect is a non-specific effect of antimicrobials in rodents.) other drug-related effects observed in these studies involved changes in red blood cell (rbc), platelet, and serum chemistry parameters. Effects on the rbc's, serum chemistry, and glycogen distribution were reversible or diminished following a recovery period.

In studies of fertility and reproductive performance, pip/tazo, administered daily by ip doses, did not affect fertility in rats and was not teratogenic in mice or rats. Postnatal growth, behavior, and reproductive performance of the f1 generation (pups resulting from mating of treated animals) were unaffected by in utero exposure of rats to pip/tazo.

Signs/Symptoms: Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Persons who exhibit allergic reactions to any of the penicillin or cephalosporin type antibiotics or to other B-Lactamase inhibitors,.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Piperacillin Sodium USP	59703-84-3	80 - 88 %	

Note: Piperacillin and Tazobactam for Injection is a monosodium salt of piperacillin and a monosodium salt of tazobactam containing a total of 2.35 mEq (54 mg) of Na+ per gram of piperacillin in the combination product.

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods for containment: This material will settle out of the air.

Methods for cleanup: Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage: Store Piperacillin and Tazobactam for Injection dry powder at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature] prior to reconstitution.

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Cryodesiccated powder.
Color:	White to off-white sterile.
Boiling Point:	Not established.
Melting Point:	> 176 °C Decomposes.
Specific Gravity:	H 0.6 (BULK){
Solubility:	Soluble in dimethylformamide.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	5%
Evaporation Rate:	Not established.
Evaporation Point:	NOT AVAILABLE
pH:	4.5 - 7 (1 G PIPERACILLIN SODIUM/5 ML SOLUTION @ 25 deg C)
Molecular Formula:	Mixture
Molecular Weight:	322.27 (C10H11N4O5S)
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Explosive Properties:	EXPLOSION HAZARDS: NOT AVAILABLE

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.
Incompatible Materials:	Strong oxidizers and strong bases.
Special Decomposition Products:	Decomposition products of this compound may include potentially hazardous byproducts, acrid, and toxic fumes.

SECTION 11 : TOXICOLOGICAL INFORMATION

Piperacillin Sodium USP :

Ingestion:	Oral - Rat LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intravenous. - Rat LD50 : 2260 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50 : 4900 mg/kg [Behavioral - Convulsions or effect on seizure threshold Behavioral - Changes in motor activity (specific assay) Lungs, Thorax, or Respiration - Respiratory stimulation] Intraperitoneal. - Rat LD50 : 7600 mg/kg [Behavioral - Convulsions or effect on seizure threshold Behavioral - Changes in motor activity (specific assay) Lungs, Thorax, or Respiration - Respiratory stimulation] Intraperitoneal. - Mouse LD50 : 9770 mg/kg [Behavioral - Convulsions or effect on seizure threshold Behavioral - Changes in motor activity (specific assay) Lungs, Thorax, or Respiration - Respiratory stimulation] Subcutaneous - Rat LD50 : 8800 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Tazobactam sodium :

Other Toxicological Information: Unreported - Mouse LD50 : >5 gm/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.
Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.
DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Canada WHMIS: Not Regulated.

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1
HMIS Fire Hazard: 1
HMIS Reactivity: 0
HMIS Personal Protection: F

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