

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** **Piperacillin and Tazobactam for Injection**  
**Manufacturer Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
 Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** June 02, 2011  
**SDS Revision Date:** June 01, 2015

### SECTION 2 : HAZARD(S) IDENTIFICATION

**GHS Pictograms:**



**Signal Word:** DANGER.

**GHS Class:** Serious Eye Damage. Category 1.  
 Respiratory sensitisation. Category 1.  
 Skin Irritation. Category 2.  
 Skin Sensitization. Category 1.  
 Reproductive toxicity. Effects on or via lactation.

**Hazard Statements:** Causes serious eye damage.  
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 Causes skin irritation.  
 May cause an allergic skin reaction.  
 May cause harm to breast-fed children.

**Precautionary Statements:** Obtain special instructions before use.  
 Do not breathe dust/fume/gas/mist/vapours/spray.  
 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 Avoid contact during pregnancy and while nursing.  
 Wash hands thoroughly after handling.  
 Do not eat, drink or smoke when using this product.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 In case of inadequate ventilation wear respiratory protection.  
**IF ON SKIN:** Wash with plenty of water.  
**IF INHALED:** Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
**IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
**IF exposed or concerned:** Get medical advice/attention.  
 Immediately call a POISON CENTER or doctor/physician.  
 Specific treatment (see ... on this label).  
 If skin irritation occurs: Get medical advice/attention.  
 If skin irritation or rash occurs: Get medical advice/attention.  
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
 Take off contaminated clothing and wash it before reuse.  
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

**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 %          |         |
| Tazobactam sodium       | 89785-84-2 | 12 - 20 %          |         |
| Sodium bicarbonate USP  | 144-55-8   | 2.5 - 5 %          |         |

**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

**Personnel 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, acid, 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]

**Sodium bicarbonate USP :**

**Eye:** Eye - Rabbit Standard Draize test.: 100 mg/30S (RTECS)

**Skin:** Administration onto the skin - Human Standard Draize test.: 30 mg/3D (Intermittent)

**Ingestion:** Oral - Rat LD50: 4220 mg/kg [Details of toxic effects not reported other than lethal dose value]  
Oral - Mouse LD50: 3360 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

**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

**SDS Creation Date:** June 02, 2011

**SDS Revision Date:** June 01, 2015

**MSDS Revision Notes:** Version 1 Revised. Includes revisions to: Section 1 (Revised product name); Section 7 (Storage Temperature); Section 9 (Physical State).

**Disclaimer:** The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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