1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Zosyn Galaxy (Piperacillin and Tazobactam Injection) in Galaxy® Containers (PL 2040 Plastic)

Trade Name: ZOSYN
Synonyms: (Piperacillin and Tazobactam Injection) in Galaxy® Containers (PL 2040 Plastic)
Chemical Family: Penicillin
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Frozen solution
Signal Word: DANGER

Statement of Hazard: May cause allergic or asthmatic symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.

Additional Hazard Information:
Short Term: Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

EU Indication of danger: Harmful

EU Hazard Symbols: 

EU Risk Phrases: R42/43 - May cause sensitization by inhalation and skin contact.

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piperacillin sodium</td>
<td>59703-84-3</td>
<td>261-888-6</td>
<td>Xn;R42/43</td>
<td>85</td>
</tr>
<tr>
<td>Tazobactam Sodium</td>
<td>89785-84-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>10</td>
</tr>
<tr>
<td>Dextrose</td>
<td>14431-43-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Disodium EDTA (dihydrate)</td>
<td>6381-92-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>68-04-2</td>
<td>200-675-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize generating airborne mists and vapors. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Piperacillin sodium

Pfizer Occupational Exposure Band (OEB): OEB 1 - Sensitizer (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Tazobactam Sodium

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)


Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

- Hands: Wear impervious gloves to prevent skin contact.
- Eyes: Wear safety glasses as minimum protection.
- Skin: Wear impervious protective clothing to prevent skin contact - consider use of disposable clothing where appropriate.
- Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Physical State: Frozen Solution
- Molecular Formula: Mixture
- Color: No data available.
- Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

- Chemical Stability: Stable under normal conditions of use.
- Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

- Tazobactam Sodium
  - Mouse Oral LD50 > 5000 mg/kg

- Piperacillin sodium
  - Rat Oral LD50 > 10 g/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

- Tazobactam Sodium
  - Reproductive & Fertility Rat 3 times human dose NOAEL No effects at maximum dose
  - Embryo / Fetal Development Rat Oral 14 times human dose NOAEL Not Teratogenic, No effects at maximum dose
  - Embryo / Fetal Development Mouse Oral 6 times human dose NOAEL Not Teratogenic, No effects at maximum dose

- Piperacillin sodium
  - Reproductive & Fertility Rat Oral 0.5 times human dose NOAEL No effects at maximum dose
11. TOXICOLOGICAL INFORMATION

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
- **Tazobactam Sodium**
  - Bacterial Mutagenicity (Ames) *Salmonella, E. coli* Negative
  - Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
  - *In Vitro* Cytogenetics Hamster Lung Cells Negative
  - *In Vivo* Chromosome Aberration Mouse Negative

- **Piperacillin sodium**
  - Bacterial Mutagenicity (Ames) *Salmonella* Negative
  - *In Vivo* Chromosome Aberration Mouse Bone Marrow Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
- **Tazobactam Sodium**
  - *Daphnia magna* (Water Flea) LC50 48 Hours > 8.5 mg/L

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
15. REGULATORY INFORMATION

**EU Indication of danger:** Harmful

**EU Risk Phrases:**
- R42/43 - May cause sensitization by inhalation and skin contact.

**EU Safety Phrases:**
- S22 - Do not breathe dust.
- S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

**OSHA Label:**
DANGER
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 2, Subdivision A

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**Dextrose**
- Australia (AICS): Present

**Disodium EDTA (dihydrate)**
- Australia (AICS): Present

**Piperacillin sodium**
- Australia (AICS): Present
- EU EINECS/ELINCS List: 261-868-6

**Sodium citrate**
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-675-3

**Water for Injection**
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2
16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources:   Pfizer proprietary drug development information. Publicly available toxicity information.
                 Product Stewardship Hazard Communication


Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet