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

Pfizer Inc
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1-212-573-2222

Pfizer Ltd
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United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Sultamicillin Tosylate Tablets

Trade Name: UNASYN Tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: WARNING

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

Additional Hazard Information:

Short Term: Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Repeated inhalation may result in sensitization.

Known Clinical Effects: May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. May cause mild skin rash. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

EU Indication of danger: Harmful
Irritant

EU Hazard Symbols: Xn

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>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sultamicillin Tosylate</td>
<td>83105-70-8</td>
<td>Not listed</td>
<td>Xn;R42/43</td>
<td>70</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose hydrous</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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 dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, 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

Refer to available public information for specific member state Occupational Exposure Limits.

Corn Starch
- ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
- Australia TWA = 10 mg/m³ TWA
- Belgium OEL - TWA Listed
- Bulgaria OEL - TWA Listed
- Czech Republic OEL - TWA Listed
- Greece OEL - TWA Listed
- Ireland OEL - TWAs = 10 mg/m³ TWA = 4 mg/m³ TWA
- OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total = 5 mg/m³ TWA
- Portugal OEL - TWA Listed
- Spain OEL - TWA Listed

Magnesium stearate
- ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
- Australia TWA = 10 mg/m³ TWA
- Belgium OEL - TWA Listed
- Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
- Lithuania OEL - TWA Listed
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Substance</th>
<th>OEB Classification</th>
<th>OEL or MAK (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>OEB 2 - Sensitizer</td>
<td>1000 TWA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 MAK average molecular weight 200-600</td>
</tr>
</tbody>
</table>

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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.

**Sultamicillin Tosylate**

**Pfizer Occupational Exposure Band (OEB):**

- OEB 2 - Sensitizer (control exposure to the range of >100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

**Analytical Method:**

- Analytical method available for sultamicillin. Contact Pfizer Inc for further information.

**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.

**Personal Protective Equipment:**

- Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

- **Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
- **Eyes:** Wear safety glasses or goggles if eye contact is possible.
- **Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
- **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:** Tablet
- **Color:** White
- **Molecular Formula:** Mixture
- **Molecular Weight:** Mixture

### 10. STABILITY AND REACTIVITY

- **Stability:** Stable under normal conditions of use.
- **Conditions to Avoid:** None known
- **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)

Sultamicillin Tosylate
Rat Oral LD 50 > 10 g/kg
Mouse Oral LD 50 > 10 g/kg

Magnesium stearate
Rat Oral LD 50 > 2000 mg/kg
Rat Inhalation LC 50 > 2000 mg/m³

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.

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
# 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>EU Symbol:</th>
<th>Xn</th>
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</thead>
<tbody>
<tr>
<td>EU Indication of danger:</td>
<td>Harmful, Irritant</td>
</tr>
</tbody>
</table>

### EU Risk Phrases:

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

### EU Safety Phrases:

- S22 - Do not breathe dust.
- S24 - Avoid contact with skin.
- S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

### OSHA Label:

**WARNING**

May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**

Class D, Division 2, Subdivision A

---

<table>
<thead>
<tr>
<th>Material</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
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<td>Hydroxypropyl cellulose</td>
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<tbody>
<tr>
<td>Corn Starch</td>
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- 232-679-6

<table>
<thead>
<tr>
<th>Material</th>
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<th>Australia (AICS):</th>
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<tbody>
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<td>Sodium starch glycolate</td>
<td>XU</td>
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<th>Material</th>
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<th>Material</th>
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<td>Lactose hydrous</td>
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</tbody>
</table>
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 4 - First Aid Measures.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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