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

Material Name: Amoxicillin Tablets

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>ZIMOX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as antibiotic agent</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

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

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: 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. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

EU Indication of danger: Harmful

EU Hazard Symbols: Xn

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


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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>Amoxicillin trihydrate</td>
<td>61336-70-7</td>
<td>Not listed</td>
<td>Xn;R42/43</td>
<td>75.5</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</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. 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 water, carbon dioxide, foam or dry chemical extinguishers.

Hazardous Combustion Products:  
Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures:  
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards:  
Not applicable
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 thoroughly after handling. 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.

Colloidal silicon dioxide
- Australia TWA: 2 mg/m³ TWA
- Austria OEL - MAKs: Listed
- Czech Republic OEL - TWA: Listed
- Estonia OEL - TWA: Listed
- Germany - TRGS 900 - TWAs: 4 mg/m³ TWA
- Germany (DFG) - MAK: 4 mg/m³ MAK
- Ireland OEL - TWAs: 2.4 mg/m³ TWA, 6 mg/m³ TWA
- Latvia OEL - TWA: Listed
- OSHA - Final PELs - Table Z-3 Mineral D: (80)/% SiO2) mg/m³ TWA
  - = 20 mppcf TWA
- Slovenia 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
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed
- Sweden OEL - TWAs: 5 mg/m³ LLV
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Estonia OEL - TWA Listed
France OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA
= 4 mg/m³ TWA
Latvia OEL - TWA Listed
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
Portugal OEL - TWA Listed
Romania OEL - TWA Listed
Spain OEL - TWA Listed

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.

Amoxicillin trihydrate

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)

Engineering Controls: General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. 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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Tablet
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
10. STABILITY AND REACTIVITY

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)

- **Magnesium stearate**
  - Rat Oral LD50 > 2000 mg/kg
  - Rat Inhalation LC50 > 2000 mg/m³

- **Amoxicillin trihydrate**
  - Mouse Oral LD50 > 25 g/kg
  - Rat Oral LD50 > 15 g/kg
  - Rabbit Oral LD50 > 12 g/kg
  - Rat SC LD50 > 8 g/kg

- **Microcrystalline cellulose**
  - Rat Oral LD50 > 5000 mg/kg
  - Rabbit Dermal LD50 > 2000 mg/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.

Irritation / Sensitization: (Study Type, Species, Severity)

- **Microcrystalline cellulose**
  - Skin Irritation Rabbit Non-irritating
  - Eye Irritation Rabbit Non-irritating

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

- **Amoxicillin trihydrate**
  - Embryo / Fetal Development Pig Oral 600 mg/kg/day NOEL Not teratogenic

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

Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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

**EU Symbol:**
- Xn

**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.
- S24 - Avoid contact with skin.
- S36/37 - Wear suitable protective clothing and gloves.

**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
- Class D, Division 2, Subdivision B

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**Amoxicillin trihydrate**
- Australia (AICS): Present

**Colloidal silicon dioxide**
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-545-4, EEC No. 418-260-2

**Magnesium stearate**
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-150-3

**Microcrystalline cellulose**
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-674-9

**Sodium starch glycolate**
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present
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. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

**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