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

Material Name: Anhydrous Ampicillin Hard Capsules

Trade Name: Amplital Hard Capsules
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>69-53-4</td>
<td>200-709-7</td>
<td>500 ***</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelatin</td>
<td>9000-70-6</td>
<td>232-554-6</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
*** per tablet/capsule/lozenge/suppository

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

3. HAZARDS IDENTIFICATION

Appearance: Capsules
Signal Word: WARNING

Statement of Hazard:
May cause allergic skin and respiratory reaction
May cause allergic reaction in penicillin-sensitive individuals

Additional Hazard Information:

Short Term: Allergic skin reactions might occur following direct contact with this material. Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe.

Long Term: Repeated inhalation may result in sensitization.
Known Clinical Effects: Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, 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. Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly severe. LIFE THREATENING REACTIONS HAVE OCCURRED IN SENSITIVE INDIVIDUALS. In sensitive individuals, symptoms might include skin rash, nausea, stomach discomfort, diarrhea, sore or dry mouth or sore tongue.

EU Indication of danger: Harmful
Irritant

EU Hazard Symbols:  

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 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.

4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get 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.

5. FIRE FIGHTING MEASURES

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

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate
   ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
   Australia TWA = 10 mg/m³ TWA

Titanium dioxide
   OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
   ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
   Australia TWA = 10 mg/m³ TWA

   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.

Ampicillin

   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: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

   Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
   Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
   Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
   Respiratory protection: None required under normal conditions of use. 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: Hard-gelatin Capsule

Color: No data available.
MATERIAL SAFETY DATA SHEET

Material Name: Anhydrous Ampicillin Hard Capsules
Revision date: 02-Jan-2007

10. STABILITY AND REACTIVITY

Stability: Stable
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. The information in this section describes the hazards of various forms of the active ingredient.

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

Ampicillin trihydrate
- Rat Oral LD50 10,000 mg/kg
- Mouse Oral LD50 15,200 mg/kg

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

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD 50 50 mg/kg

Ampicillin trihydrate
- Rat Oral LD 50 > 5000 mg/kg
- Rat Intraperitoneal LD 50 4500 mg/kg
- Mouse Oral LD 50 > 5000 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.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ampicillin trihydrate
- 103 Week(s) Rat Oral 750 mg/kg/day LOEL Gastrointestinal System
- 103 Week(s) Mouse Oral 1500 mg/kg/day LOEL Gastrointestinal system

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

Ampicillin trihydrate
- Fertility and Embryonic Development Rat Oral 2500 mg/kg/day LOEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ampicillin trihydrate
- Bacterial Mutagenicity (Ames) Salmonella Negative
- Mammalian Cell Mutagenicity Mouse Lymphoma Negative
- Sister Chromatid Exchange Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ampicillin trihydrate
103 Week(s) Mouse Oral 3000 mg/kg/day NOEL Not carcinogenic
103 Week(s) Female Rat Oral 1500 mg/kg/day NOEL Not carcinogenic
103 Week(s) Male Rat Oral 750 mg/kg/day LOEL Malignant tumors, Adrenal gland, Blood

Carcinogen Status: See below

Ampicillin trihydrate
IARC: Group 3

Titanium dioxide
IARC: Group 2B
OSHA: Present

Ampicillin
IARC: Group 3

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.

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
Irritant

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

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

OSHA Label:
WARNING
May cause allergic skin and respiratory reaction
May cause allergic reaction in penicillin-sensitive individuals

Canada - WHMIS: Classifications

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

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

Gelatin
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present
- EU EINECS List: 232-554-6

Titanium dioxide
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 236-675-5

Ampicillin
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS List: 200-709-7

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet