



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

Page 1 of 6

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

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

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Magnesium stearate	557-04-0	209-150-3	*
Titanium dioxide	13463-67-7	236-675-5	*
Ampicillin	69-53-4	200-709-7	500 ***

Ingredient	CAS Number	EU EINECS List	%
Gelatin	9000-70-8	232-554-6	*

**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.

## MATERIAL SAFETY DATA SHEET

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

Page 2 of 6  
Version: 1.1

**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.



# MATERIAL SAFETY DATA SHEET

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

Page 4 of 6  
Version: 1.1

Molecular Formula: Mixture Molecular Weight: Mixture

## 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/m<sup>3</sup>

#### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

#### **Ampicillin**

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

## MATERIAL SAFETY DATA SHEET

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

Page 5 of 6  
Version: 1.1

### 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:**

# MATERIAL SAFETY DATA SHEET

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

Page 6 of 6  
Version: 1.1

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