



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

Pfizer Global Manufacturing  
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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

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

### Material Name: Ampicillin Trihydrate Tablets

Trade Name: Amplital Tablets  
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	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Ampicillin trihydrate	7177-48-2	Not listed	1 g***

Ingredient	CAS Number	EU EINECS List	%
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Quinoline yellow E104	8004-92-0	Not listed	*

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: Tablets  
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. May cause allergic reaction in penicillin-sensitive individuals.

Long Term: Repeated inhalation may result in sensitization.

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**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. Based on the effects of other penicillins, in non-allergic individuals large doses are generally non-toxic. 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:** Remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical assistance if skin reaction occurs, which may be delayed. 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

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<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Magnesium stearate</b>		
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m <sup>3</sup> TWA	

<b>Microcrystalline cellulose</b>		
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA	total
	= 5 mg/m <sup>3</sup> TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	
Australia TWA	= 10 mg/m <sup>3</sup> 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.

<b>Ampicillin trihydrate</b>	
<b>Pfizer Occupational Exposure Band (OEB):</b>	OEB 2 - Sensitizer (control exposure to the range of >100ug/m <sup>3</sup> to < 1000ug/m <sup>3</sup> , provide additional precautions to protect from skin contact)

**Analytical Method:** Analytical method available for Ampicillin Trihydrate. Contact Pfizer Inc for further information.

**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:

<b>Hands:</b>	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
<b>Eyes:</b>	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Tablet	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information in this section describes the hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

#### **Ampicillin**

Rat	Oral	LD 50	> 5000 mg/kg
Rat	Intraperitoneal	LD 50	4500 mg/kg
Mouse	Oral	LD 50	> 5000 mg/kg

#### **Magnesium stearate**

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m <sup>3</sup>

#### **Microcrystalline cellulose**

Rat	Oral	LD50	> 5000 mg/kg
Rabbit	Dermal	LD50	> 2000 mg/kg

#### **Carboxymethylcellulose sodium**

Mouse	Oral	LD50	> 27,000 mg/kg
Rat	Oral	LD50	27,000 mg/kg
Rabbit	Dermal	LD50	> 2000 mg/kg

#### **Ampicillin trihydrate**

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

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

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### Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOEL Liver, Kidney, Ureter, Bladder

### 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:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

#### Ampicillin

##### IARC:

Group 3

#### Ampicillin trihydrate

##### 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.

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## 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



<b>Magnesium stearate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
<b>Microcrystalline cellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9
<b>Carboxymethylcellulose sodium</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Quinoline yellow E104</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
<b>Ampicillin trihydrate</b>	
Australia (AICS):	Present

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### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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**End of Safety Data Sheet**