



# MATERIAL SAFETY DATA SHEET

Revision date: 09-Feb-2009

Version: 1.0

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-262-8200

### Material Name: ZIMOX (Amoxicillin Trihydrate) Capsules

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

## 2. HAZARDS IDENTIFICATION

Appearance: Capsules  
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.  
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Amoxicillin trihydrate	61336-70-7	Not listed	Xn;R42/43	92.5
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Hard gelatin capsules	MIXTURE	Not listed	Not Listed	*

**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

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### 6. ACCIDENTAL RELEASE MEASURES

<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, 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. Minimize dust generation and accumulation.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Magnesium stearate

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	
Belgium OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA	except lead stearate
Lithuania OEL - TWA	Listed	
Portugal OEL - TWA	Listed	
Spain OEL - TWA	Listed	
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	
Australia TWA	= 10 mg/m <sup>3</sup> TWA	
Belgium OEL - TWA	Listed	
Estonia OEL - TWA	Listed	
France OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA = 4 mg/m <sup>3</sup> TWA	
Latvia OEL - TWA	Listed	
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA = 5 mg/m <sup>3</sup> TWA	total
Portugal OEL - TWA	Listed	
Romania OEL - TWA	Listed	

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA

Listed

### Amoxicillin trihydrate

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

### 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:

Capsule

### Color:

No data available.

### Molecular Formula:

Mixture

### 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.

### Incompatible Materials:

As a precautionary measure, keep away from strong oxidizers

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

##### **Microcrystalline cellulose**

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

##### **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

**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.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture 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.

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## 14. TRANSPORT INFORMATION

## 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



Amoxicillin trihydrate		
Australia (AICS):		Present
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

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

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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**