



# 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 Inc**  
**Pfizer Pharmaceuticals Group**  
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1-212-573-2222

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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: Sultamicillin Powder

**Trade Name:** UNASYN Powder  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sultamicillin	76497-13-7	Not listed	10
Sucrose	57-50-1	200-334-9	*
Citric acid	77-92-9	201-069-1	*

Ingredient	CAS Number	EU EINECS List	%
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Xanthan gum	11138-66-2	234-394-2	*
Cherry flavor, artificial	NOT ASSIGNED	Not listed	*
Sodium phosphate, dibasic	7558-79-4	231-448-7	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** White to off-white powder  
**Signal Word:** WARNING

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

**Short Term:** Not acutely toxic (based on animal data) . Accidental ingestion may cause effects similar to those seen in clinical use. Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe.

**Long Term:** Repeated inhalation may result in sensitization.

**Known Clinical Effects:** May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. May cause mild skin rash. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

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EU Indication of danger: Harmful

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:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If discomfort persists, get medical attention.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Water, carbon dioxide, dry chemical or foam

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

## 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.

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## 7. HANDLING AND STORAGE

**General Handling:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment.

**Storage Conditions:** Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

**Storage Temperature:** 15-30°C

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Sucrose

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

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.

### Sultamicillin

**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)

**Analytical Method:** Analytical method available for sultamicillin. 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:

**Hands:** Wear two layers of disposable gloves.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.

**Respiratory protection:** 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:

<b>Physical State:</b>	Powder	<b>Color:</b>	White to off-white
<b>Odor:</b>	Cherry	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

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### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**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.

### 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)

##### **Sultamicillin**

Rat Oral LD 50 > 6000 mg/kg  
Mouse Oral LD 50 > 6000 mg/kg  
Rat Intravenous LD 50 6820 mg/kg

##### **Carboxymethylcellulose sodium**

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

##### **Xanthan gum**

Rat Oral LD50 > 5000 mg/kg

##### **Citric acid**

Rat Oral LD50 3000 mg/kg

##### **Sucrose**

Rat Oral LD50 29.7 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)

##### **Sodium phosphate, dibasic**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

##### **Citric acid**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

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

##### **Sultamicillin**

28 Day(s) Rat Intraperitoneal 25,200 mg/kg/day LOAEL None identified  
26 Week(s) Rat Intravenous 137,000 mg/kg LOAEL None identified

##### **Carboxymethylcellulose sodium**

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

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

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Fertility and Embryonic Development	Rat	Oral	15 g/day	NOEL	No effects at maximum dose
Fertility and Embryonic Development	Rabbit	Oral	15 g/day	NOEL	No effects at maximum dose
Fertility and Embryonic Development	Mouse	Oral	15 g/day	NOEL	No effects at maximum dose

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

### 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

**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.  
S36/37/39 - 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

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## Sultamicillin

Standard for the Uniform Scheduling  
for Drugs and Poisons: Schedule 4

## Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present

## Sucrose

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 200-334-9

## Xanthan gum

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present  
EU EINECS List 234-394-2

## Citric acid

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 201-069-1

## Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances  
and their Reportable Quantities: = 2270 kg final RQ  
= 5000 lb final RQ  
Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 231-448-7

## Carboxymethylcellulose sodium

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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

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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**