MATERIAL SAFETY DATA SHEET

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

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

Material Name: Anhydrous Ampicillin Oral Suspension

Trade Name: Amplital Oral Suspension
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Citric acid	77-92-9	201-069-1	*
Silicon dioxide, NF	7631-86-9	231-545-4	*
Ampicillin	69-53-4	200-709-7	3 g####

Ingredient	CAS Number	EU EINECS List	%
Sucrose	57-50-1	200-334-9	*
Propylparaben	94-13-3	202-307-7	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Sodium saccharin	128-44-9	204-886-1	*
Sorbitol	6706-59-8	Not listed	*
Raspberry essence	MIXTURE	Not listed	*
Methylparaben	99-76-3	202-785-7	*
Sodium alginate	9005-38-3	Not listed	*
Sodium Citrate, Anhydrous	6132-04-3	Not listed	*

Additional Information:
* Proprietary
per vial/cartridge/ampule.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Powder
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.

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. The most common side effect seen during clinical use of penicillin is skin rash. Gastrointestinal effects such as diarrhea, nausea and vomiting also occur frequently following oral administration. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

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: 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.

7. HANDLING AND STORAGE

General Handling: Avoid breathing dust. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sucrose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

Silicon dioxide, NF

OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(% SiO2) mg/m^3 TWA = 20 mppcf TWA
Australia TWA	= 2 mg/m^3 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.

Ampicillin

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

Analytical Method: Analytical method available for Ampicillin. 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 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:	Powder	**Color:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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. 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

Methylparaben
Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Silicon dioxide, NF
Rat Oral LD50 10 g/kg

Propylparaben
Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal LD 50 200 mg/kg

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

Citric acid
Rat Oral LD50 3000 mg/kg

Sodium saccharin
Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/kg
Rat Intraperitoneal LD50 7100 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.

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Propylparaben
3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

Sodium saccharin
36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

Reproduction & Development Toxicity: (Duration, 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 trihydrate
IARC: Group 3

Silicon dioxide, NF

IARC: Group 3

Sodium saccharin
IARC: Group 3

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:

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

Sucrose

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

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

Carboxymethylcellulose sodium

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

Sodium saccharin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7

Citric acid

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

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

Sodium alginate

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

Sodium Citrate, Anhydrous

Australia (AICS):	Present

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 13 - Disposal Considerations.

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

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End of Safety Data Sheet