



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

Pfizer Inc
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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Anhydrous Ampicillin Children's Oral Drops

Trade Name: Amplital Children's Oral Drops, Solution
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Silica colloidal, Ph. Eur.	112945-52-5	Not listed	*
Ampicillin	69-53-4	200-709-7	2 g####

Ingredient	CAS Number	EU EINECS List	%
Potassium metabisulfite	4429-42-9	Not listed	*
Strawberry Oil	Not Assigned	Not listed	0
Purified water	7732-18-5	231-791-2	*
Polysorbate 80	9005-65-6	Not listed	*
Propylparaben	94-13-3	202-307-7	*
Sodium saccharin	128-44-9	204-886-1	*
Ethylparaben	120-47-8	204-399-4	*
Saccharin	81-07-2	201-321-0	*
Methylparaben	99-76-3	202-785-7	*
Polyethylene glycol 400	25322-68-3	Not listed	*
Monoammonium glycyrrhizinate	53956-04-0	258-887-7	*
Tartaric acid	87-69-4	201-766-0	*

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 plus sterile diluent
Signal Word: WARNING

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

Additional Hazard Information:

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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.

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: 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

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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 contact with eyes, skin and clothing. Wash thoroughly after handling.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) is to separate substances into different hazard categories and provide an exposure control and containment strategy for the compound as detailed in this section. The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to alteration when new information becomes available.

Ampicillin

Pfizer Occupational Exposure Band (OEB):	OEB 2 - Sensitizer (control exposure to the range of $>100\text{ug}/\text{m}^3$ to $< 1000\text{ug}/\text{m}^3$, 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 plus sterile diluent	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

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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

Polysorbate 80

Rat Oral LD50 25 g/kg

Propylparaben

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

Polyethylene glycol 400

Eye Irritation Rabbit Mild
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

Sodium saccharin

36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder

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54 Day(s) Rat Oral 32400 mg/kg LOEL Immune 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 trihydrate

IARC: Group 3

Silica colloidal, Ph. Eur.

IARC: Group 3

Sodium saccharin

IARC: Group 3

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.

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Saccharin

RCRA - U Series Wastes

waste number U202

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: 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



Potassium metabisulfite	
Australia (AICS):	Present
Purified water	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
Silica colloidal, Ph. Eur.	
Australia (AICS):	Present
Polysorbate 80	
Inventory - United States TSCA - Sect. 8(b)	XU

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Australia (AICS):	Present
Propylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7
Sodium saccharin	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1
Ethylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-399-4
Saccharin	
CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration only persons who manufacture are subject, no supplier notification
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 100 lb final RQ
	= 45.4 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-321-0
Methylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7
Polyethylene glycol 400	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Monoammonium glycyrrhizinate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	258-887-7
Tartaric acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-766-0
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.

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Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet