



MATERIAL SAFETY DATA SHEET

Revision date: 27-Sep-2005

Version: 1.0

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

Pfizer Animal Health
Pfizer Inc
235 East 42nd Street
New York, NY 10017

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

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

Material Name: Penicillin G Procaine and Penicillin G Benzathine Aqueous Suspension

Trade Name: Penlong XL
Synonyms: None
Chemical Family: Penicillin
Intended Use: Veterinary product; antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Penicillin G procaine	54-35-3	200-205-7	14
Penicillin G benzathine	41372-02-5	Not listed	12

Ingredient	CAS Number	EU EINECS List	%
Methylparaben	99-76-3	202-785-7	*
Propylparaben	94-13-3	202-307-7	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Povidone	9003-39-8	Not listed	*
Polysorbate 40	9005-66-7	Not listed	*
Sorbitan monopalmitate	26266-57-9	247-568-8	*
Water for injection	7732-18-5	231-791-2	*
Lecithin	8002-43-5	232-307-2	*
Sodium citrate, dihydrate	6132-04-3	Not listed	*
FD & C Red No. 3 (E 127)	16423-68-0	240-474-8	*
Sodium phosphate tribasic, anhydrous	7601-54-9	231-509-8	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Pink aqueous suspension
Signal Word: WARNING

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

Eye Contact: None known; however, direct contact with any foreign material may cause eye irritation.

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Skin Contact: May cause allergic reaction in penicillin-sensitive individuals.
Inhalation: Not expected due to physical form. May cause allergic reaction in penicillin-sensitive individuals.
Ingestion: Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use. See 'Known clinical effects', below.
Known Clinical Effects: May cause effects similar to those seen in clinical use including 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.

EU Indication of danger:

EU Hazard Symbols:



Harmful

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: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
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

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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Measures for Cleaning / Collecting: Contain the source of the spill or leak. Wipe up with a damp cloth and place in container for disposal. 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.

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 Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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: Not required for the normal use of this product.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Aqueous suspension	Color:	Pink
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

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 included in this section describes the potential hazards of various forms of the active ingredient

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

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Penicillin G procaine

Mouse Oral LD50 > 2000 mg/kg
Rat Oral LD50 > 2000mg/kg

Penicillin G benzathine

Mouse Oral LD50 2 g/kg

Methylparaben

Mouse Oral LD50 > 8 g/kg
Rat Oral LD50 2280mg/kg

Propylparaben

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

Carboxymethylcellulose sodium

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

Povidone

Rat Oral LD50 100 g/kg

FD & C Red No. 3 (E 127)

Rat Oral LD50 1840 mg/kg
Mouse Oral LD50 1264mg/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.

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

Penicillin V Potassium

14 Day(s) Rat Oral 2400 mg/kg/day NOAEL None identified
14 Day(s) Mouse Oral 2400 mg/kg/day NOAEL None identified
13 Week(s) Rat Oral 750 mg/kg/day LOEL Gastrointestinal system
13 Week(s) Mouse Oral 250 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

Carboxymethylcellulose sodium

Reproductive & Fertility-Males Rat Oral =140 mg/kg LOEL Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Penicillin V Potassium

Bacterial Mutagenicity (Ames) Negative
Cell Transformation Assay Mouse Lymphoma Positive with activation
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive without activation

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Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative with activation

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Penicillin V Potassium

2 Year(s) Rat Oral 1000 mg/kg/day NOEL Not carcinogenic
2 Year(s) Mouse Oral 1000 mg/kg/day NOEL Not carcinogenic

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

Povidone

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: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Labeling: Xn
EU Indication of danger: Harmful
EU Risk Phrases: R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases: S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

WARNING
May cause allergic skin and respiratory reaction
May cause allergic reaction in penicillin-sensitive individuals

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Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Penicillin G procaine	
EU EINECS List	200-205-7
Inventory - United States TSCA - Sect. 8(b)	Listed
Methylparaben	
EU EINECS List	202-785-7
Inventory - United States TSCA - Sect. 8(b)	Listed
Propylparaben	
EU EINECS List	202-307-7
Inventory - United States TSCA - Sect. 8(b)	Listed
Carboxymethylcellulose sodium	
Inventory - United States TSCA - Sect. 8(b)	Listed
Povidone	
Inventory - United States TSCA - Sect. 8(b)	Listed
Polysorbate 40	
Inventory - United States TSCA - Sect. 8(b)	Listed
Sorbitan monopalmitate	
EU EINECS List	247-568-8
Inventory - United States TSCA - Sect. 8(b)	Listed
Water for injection	
EU EINECS List	231-791-2
Inventory - United States TSCA - Sect. 8(b)	Listed
Lecithin	
EU EINECS List	232-307-2
Inventory - United States TSCA - Sect. 8(b)	Listed
FD & C Red No. 3 (E 127)	
EU EINECS List	240-474-8
Inventory - United States TSCA - Sect. 8(b)	Listed
Sodium phosphate tribasic, anhydrous	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
EU EINECS List	231-509-8
Inventory - United States TSCA - Sect. 8(b)	Listed

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16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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