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C27935  
C27936

## MATERIAL SAFETY DATA SHEET

V# 053069

Revision date: 03-Dec-2010

Version: 1.0

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

Pfizer Animal Health  
Pfizer Inc  
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New York, NY 10017  
1-212-573-2222

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

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

**Material Name: Penicillin G Procaine Injectable Suspension**

Trade Name:	DERAPEN
Chemical Family:	Penicillin
Intended Use:	Veterinary product used as antibiotic agent

**2. HAZARDS IDENTIFICATION**

Appearance: Sterile suspension  
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:	Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term:	Repeated inhalation may result in sensitization.
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: Harmful

**EU Hazard Symbols:****EU Risk Phrases:****Australian Hazard Classification (NOHSC):**

R42/43 - May cause sensitization by inhalation and skin contact.  
Hazardous Substance. Non-Dangerous Goods.

**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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Penicillin G procaine	54-35-3	200-205-7	Xn;R42/43	300mg/mL

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water, purified	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** 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.

**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 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:** 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 spill with absorbent material. 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.



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**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 vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Penicillin G procaine**  
**Pfizer Occupational Exposure Band (OEB):** OEB 2 - Sensitizer (control exposure to the range of  $>100\mu\text{g}/\text{m}^3$  to  $<1000\mu\text{g}/\text{m}^3$ , provide additional precautions to protect from skin contact)

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. 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 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>	Suspension	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** Strong oxidizers

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### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of various forms of the active ingredient.

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

##### **Penicillin G procaine**

Mouse Oral LD50 > 2000 mg/kg

Rat Oral LD50 > 2000 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.

#### 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

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

##### **Penicillin V Potassium**

*In Vitro* Bacterial Mutagenicity (Ames) Negative

*In Vitro* Cell Transformation Assay Mouse Lymphoma Positive with activation

Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive without activation

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:** Not listed as a carcinogen by IARC, NTP or US OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** 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.



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### 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.  
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

#### Canada - WHMIS: Classifications

WHMIS hazard class:  
Class D, Division 2, Subdivision A



#### Penicillin G procaine

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-205-7

#### Water, purified

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

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### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R42/43 - May cause sensitization by inhalation and skin contact.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.

**Prepared by:** Product Stewardship Hazard Communications  
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