



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Oct-2009

Version: 3.0

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

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### Material Name: Penicillin G potassium for injection

Trade Name:	PFIZERPEN
Chemical Family:	Penicillin
Intended Use:	Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

Appearance: White crystalline powder  
Signal Word: DANGER

Statement of Hazard: May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.  
May cause allergic skin reaction.

Additional Hazard Information:  
Short Term: Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

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:

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

Australian Hazard Classification (NOHSC):

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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### 2. HAZARDS IDENTIFICATION

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Penicillin G potassium	113-98-4	204-038-0	Xn;R42/43	*
Citric acid	77-92-9	201-069-1	Xi; R36	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium citrate	68-04-2	200-675-3	Not Listed	**

**Additional Information:** \*\* to adjust pH  
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:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**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:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

**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.

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<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, 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.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

#### Penicillin G potassium

<b>Pfizer Occupational Exposure Band (OEB):</b>	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)
<b>Analytical Method:</b>	Analytical method available for Penicillin G Potassium. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear two layers of disposable gloves.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Crystalline powder	<b>Color:</b>	White
<b>Odor:</b>	Odorless	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**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 various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

##### **Citric acid**

Rat Oral LD50 3000 mg/kg

##### **Penicillin G potassium**

Mouse Oral LD50 6257 mg/kg

Rat Oral LD50 8900 mg/kg

Rabbit Oral LD50 5848 mg/kg

#### 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)

##### **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

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### 11. TOXICOLOGICAL INFORMATION

#### 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.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Penicillin G potassium

*Daphnia Magna* LC50 48 Hours > 1000 mg/L  
*Nitzschia fonticola* (Diatom) LC50 630 Days 2000 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** 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.

### 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.  
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

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### 15. REGULATORY INFORMATION

**OSHA Label:**

DANGER

May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

May cause allergic skin reaction.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision A



**Penicillin G potassium**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	204-038-0

**Citric acid**

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

**Sodium citrate**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-675-3

### 16. OTHER INFORMATION

**Text of R phrases mentioned in Section 3**

R36 - Irritating to eyes.

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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

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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**