SAFETY DATA SHEET

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

Product Identifier

Material Name: Penicillin G potassium for injection
Trade Name: PFIZERPEN
Chemical Family: Penicillin

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Contact E-Mail: pfizer-MSDS@pfizer.com

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

Label Elements

Signal Word: Danger
Hazard Statements:
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 - May cause an allergic skin reaction
May form combustible dust concentrations in air

Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory protection
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin G potassium</td>
<td>113-98-4</td>
<td>204-038-0</td>
<td>Resp. Sens.1 (H334)</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens.1 (H317)</td>
<td></td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>68-04-2</td>
<td>200-675-3</td>
<td>Not Listed</td>
<td>**</td>
</tr>
<tr>
<td>Citric acid, anhydrous</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Not Listed</td>
<td>**</td>
</tr>
</tbody>
</table>

Additional Information: ** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of 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.
SAFETY DATA SHEET

Material Name: Penicillin G potassium for injection
Revision date: 23-Dec-2016

Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
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.

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

Precautions for Safe Handling
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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
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

Pfizer Occupational Exposure Band (OEB): OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)


Exposure Controls

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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Crystalline powder</th>
<th>Color:</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Odorless</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Penicillin V Potassium</td>
</tr>
<tr>
<td>Penicillin G potassium</td>
<td>No data available</td>
<td>Sodium citrate</td>
<td>No data available</td>
</tr>
<tr>
<td>No data available</td>
<td>1.83</td>
<td>No data available</td>
<td>Decomposition Temperature (°C):</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Penicillin G potassium for injection
Revision date: 23-Dec-2016

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
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.
Short Term: Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe (anaphylactic). 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.

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

Penicillin G potassium
  Mouse Oral LD50 6257 mg/kg
  Rat Oral LD50 8900mg/kg
  Rabbit Oral LD50 5848mg/kg

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
11. TOXICOLOGICAL INFORMATION

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: 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.

Toxicity:

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

Penicillin G potassium
*Daphnia magna* (Water Flea) 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.

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Penicillin G potassium 1.83

Mobility in Soil: No data available
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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Penicillin G potassium
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 204-038-0

Sodium citrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-675-3

Citric acid, anhydrous
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 201-069-1

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

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

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

Revision date:
23-Dec-2016

Prepared by:
Product Stewardship Hazard Communication
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