SAFETY DATA SHEET

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

Product Identifier

Material Name: Bicillin L-A

Trade Name: Bicillin L-A
Synonyms: Penicillin G benzathine injectable suspension
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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Respiratory Sensitization: Category 1
Skin Sensitization: Category 1

EU Classification:

EU Indication of danger: Harmful

EU Risk Phrases:
R42/43 - May cause sensitization by inhalation and skin contact.
R22 - Harmful if swallowed.

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
Precautionary Statements:

- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P304 + P311 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
- P342 + P313 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
- P363 - Wash contaminated clothing before reuse

Other Hazards

Australian Hazard Classification (NOHSC):


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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin G benzathine</td>
<td>41372-02-5</td>
<td>Not Listed</td>
<td>Xn;R22 Xn;R42/43</td>
<td>Acute Tox. 4 (H302) Sens. Cat. 1 (H334) Sens. Cat. 1 (H317)</td>
<td>45</td>
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</table>

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
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<tr>
<td>Povidone</td>
<td>9003-39-8</td>
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<td>8002-43-5</td>
<td>232-307-2</td>
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<td>Not Listed</td>
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<tr>
<td>Carboxymethylcellulose</td>
<td>9000-11-7</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Sodium Citrate Buffer</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
Material Name: Bicillin L-A
Revision date: 07-Mar-2015

4. FIRST AID MEASURES

Description of 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.

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: Not applicable

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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 the spill or leak. Wipe up with a damp cloth and place in container for disposal. 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 generating airborne mists and vapors. Avoid contact with eyes, skin and clothing. Avoid breathing mist or aerosols. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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
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 benzathine
- **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).
- **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**

- **Physical State:** Aqueous suspension
- **Odor:** No data available.
- **Molecular Formula:** Mixture
- **Solvent Solubility:** No data available
- **Water Solubility:** No data available
- **pH:** No data available
- **Melting/Freezing Point (°C):** No data available
- **Color:** White
- **Odor Threshold:** No data available
- **Molecular Weight:** Mixture
9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Methylparaben
No data available
Propylparaben
No data available
Povidone
No data available
Lecithin
No data available
Sodium Citrate Buffer
No data available
Penicillin V Potassium
No data available
Carboxymethylcellulose
No data available
Penicillin G benzathine
No data available

Decomposition Temperature (°C): No data available.
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 the individual ingredients. The information included in this section describes the potential hazards of various forms of the active ingredient
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.
11. TOXICOLOGICAL INFORMATION

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

**Propylparaben**
- Mouse Oral LD50 6332 mg/kg
- Mouse Sub-tenon injection (eye) LD50 200 mg/kg

**Povidone**
- Rat Oral LD50 100 g/kg

**Lecithin**
- Rat Oral LD50 > 8 ml/kg

**Penicillin G benzathine**
- Mouse Oral LD50 2 g/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)**

**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

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

**Povidone**
- IARC: Group 3 (Not Classifiable)
12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Penicillin G benzathine
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Australia (AICS):</th>
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<tr>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**Methylparaben**
- 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: 202-785-7

**Propylparaben**
- 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: 202-307-7

**Povidone**
- 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: Not Listed

### 16. OTHER INFORMATION

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

00230797
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful
R22 - Harmful if swallowed.
R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: Safety data sheets for individual ingredients. 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 7 - Handling and Storage. Updated Section 13 - Disposal Considerations. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 07-Mar-2015
Prepared by: Product Stewardship Hazard Communication

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