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

Product Identifier

Material Name: Bicillin C-R

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Bicillin C-R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>Penicillin G benzathine and Penicillin G procaine injectable suspension</td>
</tr>
<tr>
<td>Chemical Family</td>
<td>Penicillin</td>
</tr>
</tbody>
</table>

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
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P302+ P352 - 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>22.5-33.75</td>
</tr>
<tr>
<td>Penicillin G procaine</td>
<td>54-35-3</td>
<td>200-205-7</td>
<td>Xn;R42/43</td>
<td>Resp. Sens.1 (H334) Skin Sens.1 (H317)</td>
<td>15-30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>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>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lecithin</td>
<td>800-43-5</td>
<td>232-307-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<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>
Additional Information: * Proprietary
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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

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

Color: White

Odor: No data available.

Odor Threshold: No data available.

Molecular Formula: Mixture

Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: No data available

pH: No data available.

Melting/Freezing Point (°C): No data available

00230796
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient:</td>
<td>Method, pH, Endpoint, Value</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>No data available</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>No data available</td>
</tr>
<tr>
<td>Povidone</td>
<td>No data available</td>
</tr>
<tr>
<td>Lecithin</td>
<td>No data available</td>
</tr>
<tr>
<td>Penicillin G procaine</td>
<td>No data available</td>
</tr>
<tr>
<td>Penicillin G benzathine</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium Citrate Buffer</td>
<td>No data available</td>
</tr>
<tr>
<td>Penicillin V Potassium</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
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</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
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<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
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<tr>
<td>Chemical Stability</td>
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<tr>
<td>Possibility of Hazardous Reactions</td>
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</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>None known</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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  LD 50  6332 mg/kg
Mouse  Sub-tenon injection (eye)  LD 50  200 mg/kg

Povidone
Rat  Oral  LD50  100 g/kg

Lecithin
Rat  Oral  LD50  > 8 ml/kg

Penicillin G procaine
Mouse  Oral  LD50  > 2000 mg/kg
Rat  Oral  LD50  > 2000 mg/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  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)
11. TOXICOLOGICAL INFORMATION

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
<table>
<thead>
<tr>
<th>Material Name: Bicillin C-R</th>
<th>Version: 3.0</th>
</tr>
</thead>
</table>

### 15. REGULATORY INFORMATION

**Penicillin G benzathine**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

**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

**Penicillin G procaine**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 200-205-7

**Lecithin**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present

**Sodium Citrate Buffer**

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed
16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
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

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 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 7 - Handling and Storage.

Revision date: 07-Mar-2015

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