



# SAFETY DATA SHEET

Revision date: 07-Mar-2015

Version: 3.0

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## 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

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## 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

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**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 + 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  
 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):**

No data available  
Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Lecithin	8002-43-5	232-307-2	Not Listed	Not Listed	*
Carboxymethylcellulose	9000-11-7	Not Listed	Not Listed	Not Listed	*
Sodium Citrate Buffer	MIXTURE	Not Listed	Not Listed	Not Listed	*

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**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.

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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

#### 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/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, 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

**Color:** White  
**Odor Threshold:** No data available.  
**Molecular Weight:** Mixture

**Solvent Solubility:** No data available  
**Water Solubility:** No data available  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available

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### 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.

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### 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)

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### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	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

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

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### 15. REGULATORY INFORMATION

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Methylparaben</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	202-785-7
<b>Propylparaben</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	202-307-7
<b>Povidone</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Lecithin</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	232-307-2
<b>Carboxymethylcellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Sodium Citrate Buffer</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed

### 16. OTHER INFORMATION

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



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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 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**