



# SAFETY DATA SHEET

Revision date: 02-May-2018

Version: 3.1

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

### Product Identifier

**Material Name:** Bacitracin for Injection

**Trade Name:** BACITRACIN  
**Chemical Family:** Polypeptide antibiotic

### 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** Not classified as hazardous

### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** May form combustible dust concentrations in air

### Other Hazards

An Occupational Exposure Value has been established for this substance ( 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

### Hazardous

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Bacitracin	1405-87-4	215-786-2	Not Listed	100

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

### 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:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen and products of sulfur
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all firefighting 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. Avoid dust formation. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Do not allow material to contaminate ground water system.

#### Methods and Material for Containment and Cleaning Up

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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>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. 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

<b>Storage Conditions:</b>	Store as directed by product packaging.
<b>Incompatible Materials:</b>	Strong oxidising agents.
<b>Specific end use(s):</b>	Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

##### Bacitracin

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Exposure Controls

<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>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Powder	<b>Color:</b>	White to buff-colored
<b>Odor:</b>	Almost odorless	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	C66 H103 N17 O16 S	<b>Molecular Weight:</b>	1422.71

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>Solubility:</b>	Soluble: Water
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Bacitracin**

Predicted 7.4 Log D -2.663

<b>Decomposition Temperature (°C):</b>	No data available.
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<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

**Flammability:**

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

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	Strong oxidising agents.
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

<b>Short Term:</b>	May cause eye irritation. May produce allergic reactions following skin contact.
<b>Known Clinical Effects:</b>	Kidney dysfunction has been seen during clinical use. Serious allergic reactions, including anaphylaxis, have been reported.

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

**Bacitracin**

Guinea Pig	Oral	LD50	2000 mg/kg
Mouse	Oral	LD50	>3750mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Mouse Intravenous LD50 360mg/kg  
Rat Intraperitoneal LD50 190mg/kg  
Mouse Intraperitoneal LD50 300mg/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.

**Carcinogen Status:** Not listed as a carcinogen by IARC, NTP or US OSHA.

### 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:**  
**Partition Coefficient: (Method, pH, Endpoint, Value)**  
**Bacitracin**

Predicted 7.4 Log D -2.663

**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**

BACITRACIN STERILE POWDER

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### 15. REGULATORY INFORMATION

**Bacitracin**

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	215-786-2

### 16. OTHER INFORMATION

<b>Data Sources:</b>	Pfizer proprietary drug development information. Publicly available toxicity information.
<b>Reasons for Revision:</b>	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.
<b>Revision date:</b>	02-May-2018 Product Stewardship Hazard Communication
<b>Prepared by:</b>	Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**