	Sagent Pharmaceuticals, Inc.			
	Bacitracin for Injection, USP		Material Safety Data Sheet (MSDS)	
	Issue Date: Jun 29, 2009	MSDS No.: MSDS 023	Version No.: 1.0	Form Number: R-SOP-009-F001

Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Bacitracin for Injection, USP
Product Code: NDC 25021-116-30
 NDC 25021-116-31
Common/Trade Name: Baciim
Chemical Name: Bacitracin
Chemical Family: Complex Polypeptide / Anti-Infective
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials

Section 2 - Composition / Information on Ingredients


Ingredient	Qty / Vial	CAS No.
Bacitracin	50,000 units	1405-87-04

Section 3 - Hazards Identification

Primary Physical and Health Hazards: Use appropriate procedures to prevent opportunities for direct contact with the skin or eyes and to prevent inhalation.

Routes of Entry: Inhalation, eye/skin contact, or ingestion

Chemical Listed as Carcinogen: NTP: No IARC: No OSHA: No


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	Issue Date: Jun 29, 2009	MSDS No.: MSDS 023	Version No.: 1.0	Form Number: R-SOP-009-F001	Page: 2 of 7

Section 4 - First Aid Measures

- Eye Exposure:** Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
- Skin Exposure:** Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.
- Ingestion:** Flush mouth out with water immediately. Seek medical attention.
- Inhalation:** Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures

- Flash Point:** Not established
- Autoignition Temperature:** Not established
- Flammable Limits in Air:** Lower %: Not established
Upper %: Not established
- Flammable Limits:** Not established
- Extinguishing Media:** Water, carbon dioxide, or dry chemical as appropriate to the surrounding fire.
- Special Fire Fighting Procedures:** Wear self-contained breathing apparatus and protective clothing.
- Unusual Fire/Explosion Hazards:** Carbon monoxide, carbon dioxide, nitrogen oxides, and sulfur oxides

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	Bacitracin for Injection, USP			Material Safety Data Sheet (MSDS)	
	Issue Date: Jun 29, 2009	MSDS No.: MSDS 023	Version No.: 1.0	Form Number: R-SOP-009-F001	Page: 3 of 7

Section 6 - Accidental Release Measures

Clean-up: Wear recommended personal protective equipment. (See Section 8 – Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal regulations.

Storage Conditions: Store the unreconstituted product in a refrigerator at 2° to 8°C (36° to 46°C).

Section 8 - Exposure Controls / Personal Protection


Respiratory Protection: Respirators are not required.

Eye Protection: Safety glasses or goggles recommended.

Ventilation: Handle product in a well ventilated area.

Skin Protection: Disposable garments, if direct skin contact is anticipated. Disposable latex gloves recommended.

Other Protective Equipment: Not established

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Additional Exposure Precautions:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Individuals with a history of previous hypersensitivity or toxic reaction to bacitracin, impaired renal function, and concurrent use of other nephrotoxic drugs particularly streptomycin, kanamycin, polymixin B, polymixin E (colistin), and neomycin.

Exposure Limits


<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Bacitracin	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Solid	Specific Gravity:	Not established
Appearance and Odor:	White to pale buff, odorless or having light odor	Evaporation Rate:	Not established
Boiling Point:	Not established	Solubility in Water:	Freely soluble
Vapor Pressure:	Not established	pH:	5.5 – 7.5
Vapor Density:	Not established	Molecular Weight:	1422.71

Section 10 - Stability and Reactivity

Stability:	Stable
Incompatibility (Materials to avoid):	Not established
Hazardous Decomposition:	Not established

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	Issue Date: Jun 29, 2009	MSDS No.: MSDS 023	Version No.: 1.0	Form Number: R-SOP-009-F001	Page: 5 of 7

Hazardous Polymerization: Does not occur.

Conditions to Avoid: No conditions contributing to instability are known to exist.

Section 11 - Toxicological Information

Acute Toxicity

Component	Type	Route	Species	Dosage
Bacitracin	LD ₅₀	IV	Mouse	360 mg/kg
Bacitracin	LD ₅₀	Oral	Guinea Pig	2000 mg/kg
Bacitracin	LD ₅₀	Oral	Mouse	>3750 mg/kg
Bacitracin	LD ₅₀	IP	Rat	190 mg/kg
Bacitracin	LD ₅₀	IP	Mouse	300 mg/kg
Bacitracin	LD ₅₀	SC	Mouse	1300 mg/kg

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.


Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

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	Bacitracin for Injection, USP			Material Safety Data Sheet (MSDS)	
	Issue Date: Jun 29, 2009	MSDS No.: MSDS 023	Version No.: 1.0	Form Number: R-SOP-009-F001	Page: 6 of 7

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - *No*

CERCLA - *Not on this list*


SARA 313 - *Not on this list*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
 847-908-1600

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)