SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Bacitracin for Injection, USP**
Manufacturer Name:	Gland Pharma Limited
Address:	Survey No.: 143 - 148, 150 & 151, Near Gandimaisamma Cross Roads D.P. Pally, Quthubullapur Mandal - Ranga Reddy District Hyderabad, Andhra Pradesh 500 043 India
General Phone Number:	+91-40-30510999
General Fax Number:	+91-40-30510810
Emergency Phone Number:	+91-40-30510999 (Gland Pharma); +45-34-64-55-00 (Xellia Pharmaceuticals ApS)
Distributor Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
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SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word:	DANGER.
GHS Class:	Respiratory sensitisation. Category 1. Eye Irritation. Category 2. Skin Irritation. Category 2.
Hazard Statements:	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes serious eye irritation. Causes skin irritation.
Precautionary Statements:	Avoid breathing dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. IF ON SKIN: Wash with plenty of water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Specific treatment (see ... on this label). If skin irritation occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Take off contaminated clothing and wash it before reuse. Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.
Emergency Overview:	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.
Route of Exposure:	Inhalation Ingestion Eye contact Skin Absorption. Injection.
Potential Health Effects:	
Signs/Symptoms:	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses include: albuminuria, cylindruria, azotemia, rising blood levels without any increase in dosage, nausea, vomiting, pain at site of injection, and skin rashes. Occupational exposure has not been fully investigated.
Target Organs:	Kidney damage (renal failure due to tubular and glomerular necrosis).
Aggravation of Pre-Existing Conditions:	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.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Bacitracin	1405-87-4	100 by weight	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store in a cool, dry, well ventilated area away from sources of heat and incompatible materials. Keep container tightly closed when not in use. Store at refrigerated temperatures 2 to 8°C (36 to 46°F).
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A

	NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.
Color:	White to gray yellow.
Odor:	Odorless.
Odor Threshold:	Not relevant
Boiling Point:	Not determined.
Melting Point:	Not determined.
Specific Gravity:	Approximately 1
Solubility:	Soluble in water.
Vapor Density:	Not determined.
Vapor Pressure:	Not determined.
Percent Volatile:	Not determined.
Evaporation Rate:	Not determined.
pH:	Not determined.
Molecular Formula:	$C_{66}H_{103}N_{17}O_{16}S$ (API)
Molecular Weight:	1422.71
Coefficient of Water/Oil Distribution:	Not determined.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	Not determined.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Avoid heat, moisture, and sunlight.
Incompatible Materials:	May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.)
Special Decomposition Products:	Nitrogen- and sulphur oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11 : TOXICOLOGICAL INFORMATION

Bacitracin :

Acute Toxicity:	IMMEDIATE EFFECTS: Pre-existing skin and respiratory conditions. Acute Toxicity: LD50 IV Mouse: 360 mg/kg LD50 IP Rat: 190 mg/kg LD50 IP Mouse: 300 mg/kg LD50 SC Mouse: 1300 mg/kg

Bacitracin :

OSHA:	Not listed
IARC:	Not listed
NTP:	Not listed

Bacitracin :

RTECS Number:	CP0175000
Skin:	Administration onto the skin - Human TCLo: 20 pph/48H (Continuous) [Skin and Appendages - Dermatitis, allergic (After topical exposure)]
Ingestion:	Oral - Mouse LD50: >3750 mg/kg [Details of toxic effects not reported other than lethal dose value]
Chronic Effects:	None known.
Other Toxicological Information:	Intravenous. - Mouse LD50: 360 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - other changes]

Subcutaneous - Mouse LD50: 1300 mg/kg [Behavioral - somnolence (general depressed activity)]
Intraperitoneal. - Rat LD50: 190 mg/kg [Lungs, Thorax, or Respiration - other changes]
Intraperitoneal. - Mouse LD50: 300 mg/kg [Details of toxic effects not reported other than lethal dose value]

Chronic Effects: None known.

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Bacitracin :

TSCA Inventory Status: Listed

EINECS Number: 215-786-2

Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

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Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.