

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** Polymyxin B for Injection, USP  
**Manufacturer Name:** Gland Pharma Limited  
**Address:** Survey No.: 143 - 148, 150 & 151, Near Gandimaisamma Cross Roads  
 D.P. Pally, Quthbullapur 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:** November 14, 2012  
**SDS Revision Date:** August 01, 2015

### SECTION 2 : HAZARD(S) IDENTIFICATION

**GHS Pictograms:**



**Signal Word:** WARNING.

**GHS Class:** Acute Inhalation Toxicity, Category 4.  
 Acute Oral Toxicity, Category 4.

**Hazard Statements:** Harmful if inhaled.  
 Harmful if swallowed.

**Precautionary Statements:** Avoid breathing dust/fume/gas/mist/vapours/spray.  
 Wash hands thoroughly after handling.  
 Do not eat, drink or smoke when using this product.  
 Use only outdoors or in a well-ventilated area.  
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.  
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 Call a POISON CENTER or doctor/physician if you feel unwell.  
 Rinse mouth.  
 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: fever, urticarial rash, pain (severe) at intramuscular injection sites, and thrombophlebitis at intravenous injection sites.

**Target Organs:** Kidney and nervous system, based on clinical use as described in the Physicians Desk Reference.

**Aggravation of Pre-Existing Conditions:** Individuals with a prior history of hypersensitivity reactions to polymyxins, impaired renal function, and concurrent use of other nephrotoxic drugs particularly bacitracin, streptomycin, neomycin, kanamycin, gentamicin, tobramycin, amikacin, cephaloridine, paromomycin, viomycin, and colistin.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Polymyxin B Sulfate	1405-20-5	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.

<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
<b>Ingestion:</b>	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.
<b>Other First Aid:</b>	For Adverse Event Information, please call (800) 551-7176.

## SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	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.
<b>Extinguishing Media:</b>	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.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	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

<b>Personnel Precautions:</b>	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.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	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

<b>Handling:</b>	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.
<b>Storage:</b>	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 between 15°C to 30°C (59°F to 86°F).
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	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.
<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	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 ( <a href="http://www.cdc.gov/niosh/npptl/topics/respirators/">http://www.cdc.gov/niosh/npptl/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.
Color:	White to off-white.
Odor:	Odorless.
Odor Threshold:	Not relevant
Boiling Point:	Not determined.
Melting Point:	Not determined.
Specific Gravity:	Approximately 1
Solubility:	Soluble.
Vapor Density:	Not determined.
Vapor Pressure:	Not determined.
Percent Volatile:	Not determined.
Evaporation Rate:	Not determined.
pH:	Not determined.
Molecular Formula:	Variable – sulfate salts of polypeptides
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

**Polymyxin B Sulfate :**

**Acute Toxicity:** IMMEDIATE EFFECTS: Eye, skin, and respiratory irritation may occur. Exposure may cause allergic reactions in certain individuals and cross-allergenicity with penicillin-allergic individuals.

**Polymyxin B Sulfate :**

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

**Polymyxin B Sulfate :**

<b>Acute Effects:</b>	Eye, skin, and respiratory irritation may occur. Exposure may cause allergic reactions in certain individuals and cross-allergenicity with penicillin-allergic individuals.
<b>Ingestion:</b>	Oral - Rat LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50 : >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
<b>Chronic Effects:</b>	DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.
<b>Chronic Effects:</b>	DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.

## SECTION 12 : ECOLOGICAL INFORMATION

<b>Ecotoxicity:</b>	No ecotoxicity data was found for the product.
<b>Environmental Stability:</b>	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

---

**Polymyxin B Sulfate :**

TSCA Inventory Status: Not listed

Canada DSL: Not listed

---

## SECTION 16 : ADDITIONAL INFORMATION

---

**HMIS Ratings:**

HMIS Health Hazard: 1\*

HMIS Fire Hazard: 0

HMIS Reactivity: 0

HMIS Personal Protection: X

SDS Creation Date: November 14, 2012

SDS Revision Date: August 01, 2015

MSDS Revision Notes: GHS Update

**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.

Copyright© 1996-2015 Actio Corporation. All Rights Reserved.