

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Daptomycin for Injection**
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
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SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: WARNING.

GHS Class: Specific Target Organ Toxicity -STOT Repeated exposure RE. Category 2 (Oral, Skeletal muscle and Peripheral nerve).
 Skin Sensitization. Category 1.

Hazard Statements: May cause damage to organs through prolonged or repeated exposure.
 May cause an allergic skin reaction.

Precautionary Statements: Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF ON SKIN: Wash with plenty of water.
 Get medical advice/attention if you feel unwell.
 Specific treatment (see ... on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 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:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Anaphylaxis/hypersensitivity reactions have been reported with the use of antibacterial agents, including Daptomycin for Injection, and may be lifethreatening. If an allergic reaction to Daptomycin for Injection occurs, discontinue the drug and institute appropriate therapy.

Aggravation of Pre-Existing Conditions: Hypersensitivity to Daptomycin.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Daptomycin	103060-53-3	100 %	

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.
Note to Physicians:	Overdosage : In the event of overdosage, supportive care is advised with maintenance of glomerular filtration. Daptomycin is cleared slowly from the body by hemodialysis (approximately 15% of the administered dose is removed over 4 hours) and by peritoneal dialysis (approximately 11% of the administered dose is removed over 48 hours). The use of highflux dialysis membranes during 4 hours of hemodialysis may increase the percentage of dose removed compared with that removed by lowflux membranes.
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. Corrosive hydrogen chloride

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

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. Employees with known allergies to Daptomycin or related antibiotics should consult a health and/or safety professional prior to handling open containers of this material.
Storage:	For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert. [Store at controlled room temperature from 2 to 8°C (35.6 to 46.4°F)]. Keep dry, and away from sources of ignition.
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 dust, 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

Daptomycin:

Guideline ACGIH: Not established.
Guideline OSHA: Not established.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State: Lyophilized powder.
Color: Pale yellow, light brown.
Odor: Slightly musty
Odor Threshold: Not applicable.
Boiling Point: Not established.
Melting Point: Not established.
Specific Gravity: Not established.
Solubility: Soluble in water.
Vapor Density: Not established.
Vapor Pressure: Not established.
Percent Volatile: Not established.
pH: 5-6 (1% aqueous solution)
Molecular Formula: C₇₂ H₁₀₁ N₁₇ O₂₆
Molecular Weight: 1619.71
Coefficient of Water/Oil Distribution: Not established.
Flash Point: Not established.
Flash Point Method: Not established.
Auto Ignition Temperature: Not established.
VOC Content: Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.
Reactivity: No applicable information available.
Hazardous Polymerization: Not reported.
Conditions to Avoid: Protect from freezing.
Incompatible Materials: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.)
Special Decomposition Products: If heated to very high temperatures, the product may form hazardous decomposition products such as oxides of carbon and nitrogen and corrosive hydrogen chloride.

SECTION 11 : TOXICOLOGICAL INFORMATION

Daptomycin:

Skin: Dermal LD₅₀ >500 mg/kg, rabbit; no deaths or toxicity.
Inhalation: Inhalation LC₅₀ >2000 mg/m³, rat (4 hours); no deaths.
Ingestion: Oral LD₅₀ >2000 mg/kg, rat, no deaths or toxicity.
Carcinogenicity: Longterm carcinogenicity studies in animals have not been conducted to evaluate the carcinogenic potential of Daptomycin for Injection. Not expected to be carcinogenic in humans.
Mutagenicity: Neither mutagenic nor clastogenic potential was found in a battery of genotoxicity tests, including the Ames assay, a mammalian cell gene mutation assay, a test for chromosomal aberrations in Chinese hamster ovary cells, an in vivo micronucleus assay, an in vitro DNA repair assay, and an in vivo sister chromatid exchange assay in Chinese hamsters.
Reproductive Toxicity: Daptomycin did not affect the fertility or reproductive performance of male and female rats when administered intravenously at doses up to 150 mg/kg/day, which is approximately 9 times the estimated human exposure level based upon AUCs. Not expected to cause reproductive effects.
Other Toxicological Information: Daptomycin is present in human milk but is poorly bioavailable orally. In a single case study, daptomycin was administered daily for 28 days to a nursing mother at an IV dose of 6.7 mg/kg/day, and samples of the patient's breast milk were collected over a 24hour period on day 27. The highest measured concentration of daptomycin in the breast milk was 0.045 mcg/mL. The calculated maximum daily daptomycin dose to the infant (assuming mean milk consumption of 150 mL/kg/day) was 0.1% of the maternal dose (6.7 mg/kg/day). Caution should be exercised when daptomycin is administered to a nursing woman.

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.
IATA Shipping Name: Non regulated.
IATA UN Number: Non regulated.
IMDG UN Number : Non regulated.
IMDG Shipping Name : Non regulated.

SECTION 15 : REGULATORY INFORMATION

Daptomycin :

TSCA Inventory Status: Not listed
SARA: Not listed
Section 304 RQ: Not listed
CERCLA Section 302: Not listed
California PROP 65: Not 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:

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