

SAFETY DATA SHEET

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Revision Number: 3

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SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product identifier

Product name: Meropenem for Injection

1.2. Relevant identified uses of the substance or mixture

Product Name: Meropenem for Injection (Vial)

Product Use: Pharmaceutical product used as antibacterial treatment

1.3. Details of the responsible party of the safety data sheet

Manufacturer

Gland Pharmaceuticals
Survey No. 143-148, 150 & 151,
Near Gandimaisamma Cross Roads
D.P. Pally, Dundigal Post, Dundigal – Gandimaisamma Mandal
Medchal - Malkajgiri District
Hyderabad 500043, Telangana, India
+91 40-30510999

Distributor

Xellia Pharmaceuticals
2150 East Lake Cook Road
Buffalo Grove, IL 60089
USA
+1 833 657 3519

Email address for the competent person responsible for the safety data sheet: sales@xellia.com

Manufacturer

Xellia Pharmaceuticals ApS
Dalslandsgade 11
2300 Copenhagen S
Denmark
+45 3264 5500

Distributor

Xellia Pharmaceuticals
2150 East Lake Cook Road
Buffalo Grove, IL 60089
USA
+1 833 657 3519

Email address for the competent person responsible for the safety data sheet: sales@xellia.com

1.4. Emergency telephone number

Poison Control Center (USA): +1 877 800 5553

CHEMTREC (USA Transportation): +1 800 424 9300

CANUTREC (Canadian Transportation): +1 613 996 6666

EU: <http://apps.who.int/poisoncentres/>

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Skin Irrit. 2; Eye Irrit. 2, Skin Sens. 1, Inhal. Sens. 1.

2.2. Label elements



DANGER

H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352: IF ON SKIN: wash with plenty of water/

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P321: May need specific treatment if exposed
P332+P317: If skin irritation occurs: Get medical help.
P337+P317: If eye irritation persists: Get medical help.
P362+P364: Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

The substance is not considered PBT/vPvB, or endocrine disruptive according to the criteria in the CLP regulation.

SECTION 3: Composition/Information on Ingredients

3.1 Substances:

Active component	CAS #	EC/List #
Meropenem trihydrate	119478-56-7	642-885-1

REACH reg. #: Not registered, exempted

SECTION 4: First Aid Measures

4.1. Description of first aid measures

Eye contact: Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.
Skin contact: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.
Ingestion: Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.
Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

4.2. 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

4.3. Indication of any immediate medical attention and special treatment needed

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency center, treat symptomatically.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives.

5.2. Special hazards arising from the substance or mixture

General hazards:	May be combustible at high temperature.
Hazardous combustion products:	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
Unsuitable extinguishing media:	None
Specific methods:	Not available

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment, and emergency response

Wear personal protective equipment to avoid exposure – see section 8. Avoid generation of dust.

6.2. Environmental precautions

Water spill:	Do not empty into drains.
Land spill:	Vacuum material with appropriate dust collection in place. Be aware of potential for dust explosion when using electrical equipment. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.
Release notes:	If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities.

6.3. Methods and materials for containment and cleaning up

Contain dry material by lightly misting with water, followed by sweeping carefully so as not to generate dust, or vacuuming. Ensure the vacuum is fitted with an appropriate dust filter so dust is not re-introduced into the air. Be aware of the potential for dust explosion when using electrical equipment.

6.4. References to other sections

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

- For large quantities:** Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed TWA for an eight-hour exposure. With adequate ventilation, respiratory protection may not be needed. In the absence of adequate ventilation, suitable respiratory protection is required. The need for additional personal protective equipment including respirators, eye and skin protection should be based on a job-specific risk assessment. Additional personal protective equipment may include chemical-resistant gloves and body covering, goggles, and face shield. Adequate eye protection is always required.
- For small quantities:** Keep dry and away from sources of ignition. Keep the container tightly closed when not in use.
- Work hygienic practices:** Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

7.2. Conditions for safe storage, including any incompatibilities

Store securely, inaccessible for unauthorized persons. Keep dry and away from sources of ignition. Store at 20 - 25°C (68 - 77°F) in original, unopened package or container.

7.3. Specific end uses

See section 1.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	ppm	mg/ m ³	ppm	mg/ m ³	ppm	mg/ m ³
Meropenem (CAS # 119478-56-7)	N/A	N/A	N/A	N/A	N/A	0.1

Other country exposure limits: Not listed.

This product does not contain any hazardous materials with occupational exposure established by the region-specific regulatory bodies.

8.2. Exposure controls

Appropriate engineering controls: If dust is generated, provide local exhaust ventilation to control airborne levels.

PERSONAL PROTECTIVE EQUIPMENT:

- Eyes and face:** Wear safety glasses with side shields or goggles as appropriate when handling this material.
- Skin:** Chemical resistant gloves (nitrile or latex) and body covering.
- Respiratory:** Use an approved respirator suitable to provide level of protection required.
- Comments:** This material may cause sensitization or an allergic response with minimal exposure. Under conditions of overexposure, the material may be hazardous.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

- (a) **Physical state:** Solid
- (b) **Color:** White to pale yellow
- (c) **Odor:** Not available
- (d) **Melting point/freezing point:** Not available
- (e) **Boiling point or initial boiling point and boiling range:** Not available
- (f) **Flammability:** Flammable but not classified
- (g) **Lower and upper explosion limit:** Not applicable for solids
- (h) **Flash point:** Not applicable for solids
- (i) **Auto-ignition temperature:** Not available
- (j) **Decomposition temperature:** Not available
- (k) **pH:** 7.3-8.3 in saturated solution
- (l) **Kinematic viscosity:** Not applicable for solids.
- (m) **Solubility:** 5.63 g/L
- (n) **Partition coefficient n-octanol/water (log value):** -0.6
- (o) **Vapor pressure:** Not available
- (p) **Density and/or relative density:** Not available
- (q) **Relative vapor density:** Not available
- (r) **Particle characteristics:** Crystalline Powder

9.2. Other information:

Not available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization has not been reported.

10.4. Conditions to avoid

Incompatible materials, dust generation, excess heat, alkaline materials, strong oxidants, exposure to moist air or water.

10.5. Incompatible materials

Strong oxidants, moisture.

10.6. Hazardous decomposition products

Nitrogen oxides, carbon monoxide, and carbon dioxide.

SECTION 11: Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute dermal LD50:	Not available
Acute oral LD50:	> 5000 mg/kg (rat and mouse)
Acute inhalation LC50:	Not available
Eye effects:	Based on available data the classification criteria are not met.
Skin effects:	Based on available data the classification criteria are not met.
Sensitization:	Beta-lactam antibiotics have sensitizing effects and classifications.
Target organ:	Headache, diarrhea, constipation, nausea, vomiting, pain, redness/pain/swelling at the injection site, tingling sensation, difficulty falling asleep and sore throat/mouth.
Carcinogenicity:	Not available
Mutagenicity:	Listed by IARC: No Listed by NTP: No Listed by OSHA: No Negative on Ames and several other tests. Based on available data the classification criteria are not met.
Reproductive effects:	Did not impair fertility or harm the fetus in rats up to 1000 mg/kg/day
Teratogenic effects:	Not available

11.2. Information on other hazard

Not available

SECTION 12: Ecological Information

12.1. Toxicity

No applicable information found. Releases to the environment should be avoided.

12.2. Persistence and degradability

No applicable information found.

12.3. Bio-accumulative potential

No applicable information found.

12.4. Mobility in soil

No applicable information found.

12.5. Results of PBT and vPvB assessment

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Endocrine disrupting properties

No such properties are known to the substance.

12.7. Other adverse effects

The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods: Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport Information

14.1. UN Number or ID number

Not regulated.

14.2. UN proper shipping name

Not regulated.

14.3. Transport hazard class(es)

Not regulated.

14.4. Packing group

Not regulated.

14.5. Environmental hazards

Not regulated.

14.6. Special precautions for user

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

Proper Shipping Name: Not regulated.

CANADA TRANSPORT OF DANGEROUS GOODS

Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)

Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)

Proper Shipping Name: Not regulated.

EUROPEAN TRANSPORTATION:

ADR/RID HAZARD CLASSIFICATION: Not regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not available.

SECTION 15: Regulatory Information

15.1. Safety, health, and environmental regulation/legislation specific for the substance or mixture

EUROPEAN UNION

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** No **Chronic:** No

313 Reportable Ingredients: Not listed

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Exempt

National Response Center: US Coast Guard National Center Response Telephone
+1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed

15.2. Chemical safety assessment

No CSR is compiled because the substance is exempted.

SECTION 16: Other Information

Reason for issue: Update to include Skin and inhalation sensitization classification. Physical data from Pubchem.

Contact Information: See Section 1.

Revision summary: Third issue.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.