SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

MERONEM

Details of the supplier of the safety data sheet:
ASTRAZENECA PTY LTD
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

Emergency Telephone:
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names:
Merrem

CAS No.: Not applicable
Use: Carbapenem antibiotic for parenteral use

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Classification</th>
<th>UN GHS</th>
<th>Category</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin sensitisation</td>
<td>1B</td>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>1B</td>
<td>H334</td>
<td></td>
</tr>
<tr>
<td>Acute aquatic toxicity</td>
<td>1</td>
<td>H400</td>
<td></td>
</tr>
</tbody>
</table>
| Chronic aquatic toxicity | 1 | H410 | Very toxic to aquatic life with long lasting effects. # Refer to Section 16 'Other information'

Label elements

Signal word:
Danger

Hazard statements

H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements

P261 Avoid breathing dust.

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.

P304 + P341 : IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P342 + P311 : If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

P501 : Dispose of contents/container to an approved incineration plant.

Other hazards
May produce headache, diarrhoea, drowsiness, skin rashes or cough. May form explosive dust-air mixture if dispersed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meropenem trihydrate</td>
<td>84.6</td>
<td>119478-56-7</td>
</tr>
<tr>
<td>Hazard class #</td>
<td>Category</td>
<td>Hazard statements #</td>
</tr>
<tr>
<td>Skin sensitisation</td>
<td>1</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Carbonate</td>
<td>15.4</td>
<td>497-19-8</td>
</tr>
<tr>
<td>Hazard class #</td>
<td>Category</td>
<td>Hazard statements #</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
</tbody>
</table>

# Refer to Section 16 "Other Information"

4. FIRST-AID MEASURES

Description of first aid measures

Inhalation : Remove patient from exposure, keep warm and at rest. Obtain medical attention for symptoms of difficulty in breathing and wheeziness, however minor.

Skin Contact : Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of water. Obtain medical attention.

Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.

Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.
Most important symptoms and effects, both acute and delayed
Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media (suitable) : water spray, foam, dry powder or CO2.
Extinguishing Media (unsuitable) : Avoid high pressure media which could cause the formation of a potentially explosive dust-air mixture.

Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.

Special protective actions for fire-fighters : A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES


Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.

Methods and material for containment and cleaning up : Avoid dust generation. Wash the spillage area with water. Transfer to a container for disposal. Avoid release to the environment. See section 13.

7. HANDLING AND STORAGE

Precautions for safe handling : Avoid contact with skin and eyes. Avoid breathing dust. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. See Section 8. Procedures for handling should be in accordance with the AstraZeneca instruction on the handling of respiratory sensitisers: "Respiratory Sensitisers - Managing the Risks to Health from Exposure at Work". Minimize dust generation and accumulation. The material may form explosive dust-air mixture if dispersed. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel.

Conditions for safe storage, including any incompatibilities : Keep container tightly closed. Do not freeze.

Specific end use(s) : Not applicable, refer to Section 1

Storage temperature : 20 - 22 °C
8. EXPOSURE CONTROLS/PERSOANL PROTECTION

Control parameters

Occupational Exposure Limit Value

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
<th>Control parameters</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meropenem trihydrate</td>
<td>0,1 mg/m³</td>
<td>LTEL 8hr TWA</td>
<td>The exposure should be kept as low as possible below this level to protect against respiratory sensitisation.</td>
</tr>
</tbody>
</table>

Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses. See Section 6 for environmental precautions.

Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Respiratory protection

Use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.

Skin protection

Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Eye protection

Use goggles to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : powder
Colour : white

Other information

No other data available

10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.
Chemical stability : Stable under normal conditions.
11. TOXICOLOGICAL INFORMATION

The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation: No information available on acute toxicity. May cause effects as described under repeated exposure. (STOT)

Skin Contact: Unlikely to cause skin irritation.

Eye Contact: Causes serious eye irritation.

Ingestion: No information available.

Specific Target Organ Toxicity (STOT):

- **Single exposure**
  - Exposure routes: Oral, Inhalation
  - May produce headache, diarrhoea, drowsiness, skin rashes or cough.

- **Repeated exposure**
  - Exposure routes: Inhalation
  - Hypersensitivity reactions may occur.

Sensitisation: May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity: No information available.

Mutagenicity: This material is not considered to be genotoxic.

Reproductive toxicity: There is no evidence of a teratogenic potential or any other adverse effects on reproductive function. The substance may be excreted in breast milk at low concentrations.

12. ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects. No information on this formulation. The following information refers to active ingredient:

Toxicity:

- EC50 blue-green algae 72 H 0.026 mg/l
- EC50 Daphnia magna 48 H > 900 mg/l
  (tested at concentration above water solubility)

Effect on Effluent Treatment: There is no evidence of inhibition to the aerobic treatment process at a concentration of > 100 mg/l.

Persistence and degradability: Not rapidly degradable.
Bioaccumulative potential: The substance has low potential for bioaccumulation.

Mobility in soil:
- The substance has low mobility in soil. (pH 7.7, Koc 220).
- The substance has moderate mobility in soil. (pH 5.8, Koc 1121).
- The substance has high mobility in soil. (pH 5.0, Koc 21724).

Other adverse effects: No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods: Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.

Contaminated Packaging: Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

**ICAO/IATA**
- UN No.: 3077
- Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (MEROPENEM TRIHYDRATE)
- Class: 9
- Packing Group: III
- Environmental hazards: Environmentally hazardous

**IMO/IMDG**
- UN No.: 3077
- Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (MEROPENEM TRIHYDRATE)
- Class: 9
- Packing Group: III
- Marine pollutant: Marine pollutant

**ADR**
- UN No.: 3077
- Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (MEROPENEM TRIHYDRATE)
- Class: 9
- Label(s): 9
- Packing Group: III
- Environmental hazards: Environmentally hazardous
15. REGULATORY INFORMATION

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

Hazard statements

- H317: May cause an allergic skin reaction.
- H319: Causes serious eye irritation.
- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

The following sections contain revisions or new statements:

Minor changes: 2, 6, 7, 8, 9, 11, 13

GLOSSARY

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>COM</td>
<td>In-house occupational exposure limit</td>
</tr>
<tr>
<td>LTEL</td>
<td>Long-term exposure limit (8 hour TWA (time-weighted average))</td>
</tr>
<tr>
<td>STEL</td>
<td>Short-term exposure limit (15-minute TWA (time-weighted average))</td>
</tr>
<tr>
<td>TLV</td>
<td>Threshold Limit Value (ACGIH)</td>
</tr>
<tr>
<td>TLV-C</td>
<td>Threshold Limit Value - Ceiling limit (ACGIH)</td>
</tr>
<tr>
<td>HYG</td>
<td>An in-house analytical method for occupational exposure monitoring is available</td>
</tr>
<tr>
<td>Sk</td>
<td>Can be absorbed through skin, thus contributing to systemic effects</td>
</tr>
<tr>
<td>Sen</td>
<td>Capable of causing respiratory sensitisation</td>
</tr>
</tbody>
</table>

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.