SECTION 1: Identification

1.1. Identification
Product name: Esomeprazole Sodium for Injection

Other means of identification:
NDC 55150-184-05 (20 mg)
NDC 55150-185-05 (40 mg)

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/mixture: Pharmaceutical

1.3. Details of the supplier of the safety data sheet
AuroMedics
6 Wheellng Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number
Emergency number: 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification
- Acute Tox. 4 (Oral) H302
- Eye Irrit. 2A H319
- Skin Sens. 1 H317
- Aquatic Acute 3 H402
- Aquatic Chronic 2 H411

Full text of classification categories and H statements: see section 16

2.2. Label elements

GHS-US labeling
Hazard pictograms (GHS-US):

![GHS07](image)
![GHS09](image)

Signal word (GHS-US): Warning
Hazard statements (GHS-US):
- H302 - Harmful if swallowed
- H317 - May cause an allergic skin reaction
- H319 - Causes serious eye irritation
- H402 - Harmful to aquatic life
- H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (GHS-US):
- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P264 - Wash thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P272 - Contaminated work clothing must not be allowed out of the workplace
- P273 - Avoid release to the environment
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell
- 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
- P330 - Rinse mouth
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
- P337+P313 - If eye irritation persists: Get medical advice/attention
- P363 - Wash contaminated clothing before reuse
- P391 - Collect spillage
- P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.
2.3. Other hazards
No additional information available

2.4. Unknown acute toxicity (GHS US)
Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
</table>
| Esomeprazole sodium   | (CAS No) 161796-78-7 | 90 - 95 | Acute Tox. 4 (Oral), H302  
Eye Irrit. 2A, H319  
Skin Sens. 1, H317  
Aquatic Acute 3, H402  
Aquatic Chronic 2, H411 |

Full text of classification categories and H statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: Remove patient from exposure. Obtain medical attention if ill effects occur.
First-aid measures after skin contact: Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of soap and water. Obtain medical attention.
First-aid measures after eye contact: Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
First-aid measures after ingestion: Go into open air and ventilate suspected area.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/injuries after skin contact: May cause an allergic skin reaction.
Symptoms/injuries after eye contact: Causes eye irritation.
Symptoms/injuries after 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 if ill effects occur.

4.3. Indication of any immediate medical attention and special treatment needed
No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media: Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard: Toxic fumes may be evolved in a fire.

5.3. Advice for firefighters
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General measures: No special measures required.

6.1.1. For non-emergency personnel
No additional information available

6.1.2. For emergency responders
No additional information available

6.2. Environmental precautions
Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment: Stop the flow of material, if this is without risk.
Methods for cleaning up: Moisten spillages with water. Transfer to a container for disposal. Wash the spillage area with water.
# Section 7: Handling and Storage

## 7.1. Precautions for Safe Handling

Precautions for safe handling: Do not breathe dust. Avoid contact with skin and eyes. Minimize dust generation and accumulation. The material may form explosible 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.

## 7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in original containers. Protect from light.

# Section 8: Exposure Controls/Personal Protection

## 8.1. Control Parameters

**Esomeprazole Sodium (161796-78-7)**

Not applicable

## 8.2. Exposure Controls

**Appropriate Engineering Controls**: Local exhaust and general ventilation must be adequate to meet exposure standards.

**Hand Protection**: Use neoprene or rubber gloves.

**Eye Protection**: In case of dust production: protective goggles.

**Skin and Body Protection**: Wear suitable working clothes.

**Respiratory Protection**: Wear NIOSH approved respirator when handling.

# Section 9: Physical and Chemical Properties

## 9.1. Information on Basic Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Powder</td>
</tr>
<tr>
<td>Color</td>
<td>White to off-white</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosion limits</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>

## 9.2. Other Information

No additional information available
SECTION 10: Stability and reactivity

10.1. Reactivity
No additional information available

10.2. Chemical stability
The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions
Will not occur.

10.4. Conditions to avoid
None.

10.5. Incompatible materials
Acids.

10.6. Hazardous decomposition products
None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity: Oral: Harmful if swallowed.

**Esomeprazole Sodium for Injection**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LDS0 oral rat</td>
<td>&gt; 5314 mg/kg</td>
</tr>
<tr>
<td>ATE US (oral)</td>
<td>526.316 mg/kg body weight</td>
</tr>
</tbody>
</table>

**Esomeprazole sodium (161796-78-7)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ATE US (oral)</td>
<td>500.000 mg/kg body weight</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Not classified
Serious eye damage/irritation: Causes serious eye irritation.
Respiratory or skin sensitization: May cause an allergic skin reaction.
Germ cell mutagenicity: Not classified
Carcinogenicity: Not classified
Reproductive toxicity: Not classified
Specific target organ toxicity (single exposure): Not classified
Specific target organ toxicity (repeated exposure): Not classified
Aspiration hazard: Not classified

SECTION 12: Ecological information

12.1. Toxicity
No additional information available

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
No additional information available

12.4. Mobility in soil
No additional information available

12.5. Other adverse effects
Effect on the global warming: No known effects from this product.
**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Waste disposal recommendations: Dispose of contents/container in accordance with local/regional/national/international regulations.

**SECTION 14: Transport information**

Department of Transportation (DOT)

In accordance with DOT

Not applicable

**SECTION 15: Regulatory information**

**15.1. US Federal regulations**

No additional information available

**15.2. US State regulations**

No additional information available

**SECTION 16: Other information**

Full text of H-phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 3</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 3</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>Hazardous to the aquatic environment - Chronic Hazard Category 2</td>
</tr>
<tr>
<td>Eye Irrit. 2A</td>
<td>Serious eye damage/eye irritation Category 2A</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitization Category 1</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.