

# Esomeprazole Sodium for Injection

## Safety Data Sheet

### 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 Wheelling 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

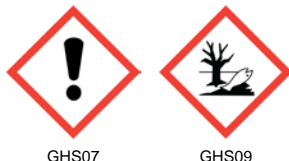
Acute Tox. 4 (Oral) H302  
Eye Irrit. 2A H319  
Skin Sens. 1 H317  
Aquatic Acute 3 H402  
Aquatic Chronic 2 H411

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

#### 2.2. Label elements

##### GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

GHS09

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.

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### 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

Name	Product identifier	%	GHS-US classification
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.

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### 6.4. Reference to other sections

No additional information available

## 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

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

### 9.2. Other information

No additional information available

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## Safety Data Sheet

### 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	
LD50 oral rat	> 5314 mg/kg
ATE US (oral)	526.316 mg/kg body weight

Esomeprazole sodium (161796-78-7)	
ATE US (oral)	500.000 mg/kg body weight

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.

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### 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:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Sens. 1	Skin sensitization Category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H402	Harmful to aquatic life
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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*