



Product name: Esomeprazole Sodium for Injection

Issue date: 04-15-22

# SDS

## Safety Data Sheet

SDS No. : 22868980415301



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## 1. Product and Company Identification

**Product name** : Esomeprazole Sodium for Injection

**Product use** : Duodenal ulcer, Gastric ulcer, Gastro-oesophageal reflux disease, Peptic ulcer, Zollinger-Ellison syndrome

**Manufacturer/ Supplier** : Hainan Poly Pharm Co. Ltd

**Address** : No.2 Xingyang Road, Guilinyang Economic Development Area, Haikou, Hainan 571127, P.R.China

**Telephone** : +86 898-36389016

**E-mail** : hnpoly@hnpoly.com

**Emergency telephone number of the company** : +86 898-36389016

## 2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

**GHS classification of the product** : Acute toxicity – oral category 4  
Sensitization – skin category 1A  
Eye damage/irritation category 2A

### Label elements

**Pictogram** : 

**Signal word** : Warning

**Hazard statement** : Harmful if swallowed  
May cause an allergic skin reaction  
Causes serious eye irritation

### Precautionary statements

**Prevention** : Wash exposed skin thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
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.

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- Response : IF SWALLOWED: Call a POISON CENTER/doctor/if you feel unwell.  
Rinse mouth.  
IF ON SKIN: Wash with plenty of water.  
If skin irritation or rash occurs: Get medical advice/attention.  
Specific treatment (see section 4 on this SDS)  
Wash contaminated clothing before reuse.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.
- Disposal : Dispose of contents/container in accordance with local/regional/national/international regulations.
- Hazards not otherwise classified : No specific dangers known, if the regulations/notes for storage and handling are considered.

## 3. Composition / Information on Ingredients

Chemical nature: mixture

Components

Chemical Name	CAS-No.	Concentration
Esomeprazole Sodium	161796-78-7	95-99%
Ethylenediaminetetraacetic acid disodium salt dihydrate	6381-92-6	1-5%

## 4. First-Aid Measures

Description of first aid measures

- Inhalation : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
- Skin contact : Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- Eye contact : Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
- Ingestion : Never give anything by mouth to an unconscious person. Rinse mouth with water. Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Seek medical attention.
- Most important symptoms and effects, both acute and delayed : Aside from the information found under Description of first aid measures (above) and Indication of immediate medical attention and special treatment needed (below), any additional important symptoms and effects are described in Section 11: Toxicology Information.

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Indication of any immediate medical attention and special treatment needed

Note to physician : Treatment of exposure should be directed at the the clinical condition of the patient.

## 5 : Fire-Fighting Measures

Suitable extinguishing media : Water fog or fine spray. Dry chemical fire extinguishers. Carbon dioxide fire extinguishers.

Unsuitable extinguishing media : No data available.

Special hazards arising from the substance or mixture

Hazardous combustion products : During a fire, smoke may contain the original material in addition to combustion products of varying composition which may be toxic and/or irritating. Combustion generates toxic fumes of the following : Carbon oxides, nitrogen oxides (NOx), sulfur oxides, sodium oxides.

Advice for firefighters

Special protective equipment for firefighters : Wear positive-pressure self-contained breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, trousers, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

## 6 : Accidental release measures

Personal precautions, protective equipment and emergency procedures : Avoid skin contact. Use personal protective equipment.

Environmental precautions : Contain contaminated water/firefighting water.

Methods and materials for containment and cleaning up : Contain spilled material if possible. Keep in suitable, closed containers for disposal.

## 7 : Handling and storage

Advice on safe handling : Avoid contact with the skin, eyes and clothing. Avoid breathing dust.

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Conditions for safe storage, including any incompatibilities : Keep container tightly closed in a dry and well-ventilated place. Keep in a dry place. Storage conditions: Refrigerator.

## 8 : Exposure Controls/Personal Protection

Control parameters : No data available.

Personal protective equipment

Respiratory protection : Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines.

Hand protection : Use gloves chemically resistant to this material.Examples of acceptable glove barrier materials include: Natural rubber ("latex").

Eye protection : Safety glasses.

Skin and body protection : Lab coat or coveralls.

## 9 : Physical and chemical properties

Form : powder, lyophilized

Colour : white

Odour : none

pH : 10.0~11.0

Melting point : no data available

Boiling point : no data available

Flash point : no data available

Thermal decomposition temperature : no data available

Density : no data available

Water solubility : no data available

Viscosity, dynamic : not applicable

## 10 : Stability and Reactivity

Reactivity : No hazardous reactions if stored and handled as prescribed/indicated.

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- Chemical stability : The product is stable if stored and handled as prescribed/indicated.
- Possibility of hazardous reactions : This material is considered stable.
- Conditions to avoid : No information available.
- Incompatible materials : Strong acids.Strong oxidizers.
- Hazardous decomposition products : No hazardous decomposition products if stored and handled as prescribed/indicated.

## 11 : Toxicological information

### Information on toxicological effects

#### Acute toxicity

Acute Toxicity: oral

#### Esomeprazole Sodium

LD50(rat): >300 and ≤ 2000 mg/kg bodyweight

#### Skin irritation/corrosion

Not irritating.

#### Serious eye damage/irritation

Causes serious eye irritation.

#### Respiratory or skin sensitisation

May cause an allergic skin reaction.

#### Germ cell mutagenicity

Evidence analysis showed that the substance did not induce gene mutations.

#### Carcinogenicity

Evidence analysis showed that the substance was not a carcinogen.

#### Reproductive toxicity

Animal tests showed no developmental toxicity.

#### STOT-single exposure

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No information available

STOT-repeated exposure

No information available

Aspiration hazard

No information available

## 12 : Ecological information

Aquatic Toxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

## 13 : Disposal considerations

Product : Observe national and local legal requirements.

Contaminated packaging : Dispose in accordance with local, state, and federal regulations.

## 14 : Transport Information

Land transport

DOT

UN number : not applicable

UN proper shipping name : not applicable

Transport hazard class(es) : not applicable

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Packing group : not applicable

Sea transport

IMDG

UN number : not applicable

UN proper shipping name : not applicable

Transport hazard class(es) : not applicable

Packing group : not applicable

Air transport

IATA/ICAO

UN number : not applicable

UN proper shipping name : not applicable

Transport hazard class(es) : not applicable

Packing group : not applicable

## 15 : Regulatory information

Federal Regulations

United States TSCA Inventory (TSCA:

All components of this product are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

EPCRA 311/312 (Hazard categories): Acute

CA Prop. 65:

There are no listed chemicals in this product.

NFPA Hazard codes:

Health : 2      Fire: 1      Reactivity: 0      Special:

HMIS III rating

Health: 2      Flammability: 1      Physical hazard: 0

## 16 : Other information

SDS Prepared by:

Cairui Chemical Technology (Shanghai) CO.,LTD

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