

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Substance  
Substance name : Esomeprazole sodium  
Chemical name : Esomeprazole sodium  
CAS-No. : 161796-78-7  
Product code : 202200270

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### Relevant identified uses

Use of the substance/mixture : Scientific research and development  
Technical testing and analysis  
For professional use only  
Function or use category : Laboratory chemicals

##### Uses advised against

Restrictions on use : Not for food, drug or home use

#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302  
Serious eye damage/eye irritation, Category 2 H319  
Skin sensitisation, Category 1 H317  
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Toxic to aquatic life with long lasting effects. Causes serious eye irritation. May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

GHS09

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed.

H317 - May cause an allergic skin reaction.

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Precautionary statements (CLP)

- H319 - Causes serious eye irritation.
- H411 - Toxic to aquatic life with long lasting effects.
- : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P272 - Contaminated work clothing should not be allowed out of the workplace.
- P273 - Avoid release to the environment.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P301+P312 - IF SWALLOWED: Call a POISON CENTRE or 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.
- P321 - Specific treatment (see supplemental first aid instruction on this label).
- 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.
- P362+P364 - Take off contaminated clothing and wash it before reuse.
- P391 - Collect spillage.
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

**No labelling required**

### 2.3. Other hazards

#### Other information

- : Active substance (in pharmaceutical products).
- Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Esomeprazole sodium	CAS-No.: 161796-78-7	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms persist, call a physician.
- First-aid measures after eye contact : Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

- Symptoms/effects after skin contact : May cause an allergic skin reaction.

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Symptoms/effects after eye contact : Causes serious eye irritation. Redness, pain.

### 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. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.

Unsuitable extinguishing media : Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

#### For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

#### For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.

Packaging materials : Keep in original containers.

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

##### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

##### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

##### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White, almost white.
Appearance	: Powder.
Molecular mass	: 367.4 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 10.3 – 11.3 (2%, Aqueous solution)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 100 – 1000 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Particle size : Not available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

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

Acute toxicity (oral) : Harmful if swallowed.  
Acute toxicity (dermal) : Not classified (Lack of data)  
Acute toxicity (inhalation) : Not classified (Lack of data)

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

LD50 oral rat	> 300 – ≤ 2000 mg/kg
---------------	----------------------

Skin corrosion/irritation	: Not classified (Lack of data) pH: 10.3 – 11.3 (2%, Aqueous solution)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 10.3 – 11.3 (2%, Aqueous solution)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

### 11.2. Information on other hazards

No additional information available

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

Esomeprazole sodium (161796-78-7)	
LC50 - Fish [1]	> 1 mg/l (96 Hours) (estimated value)
EC50 - Crustacea [1]	> 1 mg/l (48 Hours) (estimated value)
ErC50 algae	> 1 mg/l (72 Hours) (estimated value)
NOEC chronic fish	> 0.1 – ≤ 1 mg/l (estimated value)
NOEC chronic crustacea	> 1 mg/l (estimated value)
NOEC chronic algae	> 1 mg/l (estimated value)

#### 12.2. Persistence and degradability

Esomeprazole sodium (161796-78-7)	
Persistence and degradability	Not rapidly degradable

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

No additional information available

### SECTION 14: Transport information


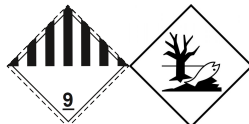
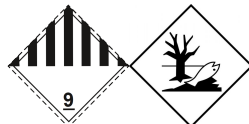
In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077
<b>14.2. UN proper shipping name</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.

# Esomeprazole sodium


## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
<b>Transport document description</b>		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
<b>14.3. Transport hazard class(es)</b>		
9	9	9
		
<b>14.4. Packing group</b>		
III	III	III
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 

Tunnel restriction code (ADR) : -

#### Transport by sea

Special provisions (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Tank special provisions (IMDG) : TP33  
Stowage category (IMDG) : A  
Stowage and handling (IMDG) : SW23

### Air transport

PCA Excepted quantities (IATA) : E1  
PCA Limited quantities (IATA) : Y956  
PCA limited quantity max net quantity (IATA) : 30kgG  
PCA packing instructions (IATA) : 956  
PCA max net quantity (IATA) : 400kg  
CAO packing instructions (IATA) : 956  
CAO max net quantity (IATA) : 400kg  
Special provisions (IATA) : A97, A158, A179, A197, A215  
ERG code (IATA) : 9L

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Indication of changes:

Classification of the substance or mixture.

#### Indication of changes

Section	Changed item	Comments
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
1.1	CAS-No.	<b>Added</b>

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
1.2	Restrictions on use	<b>Modified</b>
1.2	Use of the substance/mixture	<b>Modified</b>
1.2	Main use category	<b>Removed</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
4.2	Symptoms/effects after skin contact	<b>Added</b>
4.2	Symptoms/effects after eye contact	<b>Added</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>
6.1	General measures	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.2	Environmental precautions	<b>Added</b>
6.3	For containment	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Eye protection	<b>Added</b>
8.2	Respiratory protection	<b>Added</b>
8.2	Hand protection	<b>Modified</b>
8.2	Appropriate engineering controls	<b>Modified</b>
8.2	Skin and body protection	<b>Modified</b>
9	pH	<b>Added</b>
9	Molecular mass	<b>Added</b>

# Esomeprazole sodium

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
9	Colour	Added
9	Appearance	Added
10.1	Reactivity	Removed
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Added
12.1	Ecology - general	Removed
12.1	NOEC chronic fish	Added
12.1	NOEC chronic crustacea	Added
12.1	NOEC chronic algae	Added
12.1	ErC50 algae	Added
12.1	LC50 - Fish [1]	Added
12.1	EC50 - Crustacea [1]	Added

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

**DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. 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.