

Pantoprazole Sodium for Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Pantoprazole Sodium for Injection
Other means of identification : NDC55150-202-10 (carton of 10 vials); NDC 55150-202-25 (carton of 25 vials)

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

Use of the substance/mixture : Pharmaceutical product for the treatment of gastrointestinal disorders

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

Classification (GHS-US)

Acute Tox. 4 (Oral) H302
Carc. 1B H350

Full text of H-phrases: see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

GHS08

Signal word (GHS-US) : Danger
Hazard statements (GHS-US) : H302 - Harmful if swallowed
H350 - May cause cancer
Precautionary statements (GHS-US) : P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell
P308+P313 - If exposed or concerned: Get medical advice/attention
P330 - Rinse mouth
P405 - Store locked up
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

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3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Pantoprazole sodium	(CAS No) 138786-67-1	95 - 100	Acute Tox. 4 (Oral), H302 Carc. 1B, H350 Aquatic Acute 3, H402
Edetate disodium	(CAS No) 6381-92-6	1 - 3	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

- Symptoms/injuries after inhalation : None anticipated during normal product use.
- Symptoms/injuries after skin contact : None anticipated during normal product use.
- Symptoms/injuries after eye contact : May cause eye irritation.
- Symptoms/injuries after ingestion : Harmful if swallowed.

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 : Extinguish fires with CO₂, extinguishing powder, foam, or water.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : None known.

5.3. Advice for firefighters

- Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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 : Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

6.4. Reference to other sections

No additional information available

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store as directed by product packaging.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eye protection : Wear safety glasses or goggles if eye contact is possible.

Skin and body protection : Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection : Wear NIOSH approved respirator if workplace exposure standards are exceeded.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Freeze-dried powder.

Color : White to off-white

Odor : Odorless.

Odor threshold : No data available

pH : No data available

Melting point : 149-150°F

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

Explosion limits : No data available

Explosive properties : No data available

Oxidizing properties : No data available

Vapor pressure : No data available

Relative density : No data available

Relative vapor density at 20 °C : No data available

Solubility : No data available

Log Pow : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available

Viscosity, kinematic : No data available

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Viscosity, dynamic : No data 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

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Pantoprazole Sodium for Injection	
ATE US (oral)	747.000 mg/kg body weight
Pantoprazole sodium (138786-67-1)	
LD50 oral rat	747 mg/kg
ATE US (oral)	747.000 mg/kg body weight
Sodium hydroxide (1310-73-2)	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350.000 mg/kg

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : May cause cancer.

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

Sodium hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and degradability

No additional information available

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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 ecological damage caused by 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 regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

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
Carc. 1B	Carcinogenicity Category 1B
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H350	May cause cancer
H402	Harmful to aquatic life

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