

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Pantoprazole Sodium for Injection, 40 mg

1.2. Intended Use of the Product

Use Of The Substance/Mixture: Pantoprazole Sodium for Injection is a proton pump inhibitor (PPI) for intravenous use.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

Manufacturer

Lek d.d.

Verovškova 57

1526 Ljubljana, Slovenija

+386 1 580 21 11

Info.lek@sandoz.com

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Acute Tox. 4 (Oral) H302

Skin Irrit. 2 H315

Eye Irrit. 2 H319

STOT SE 3 H335

STOT RE 2 H373

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Warning

Hazard Statements (GHS-US/CA)

: H302 - Harmful if swallowed.

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

H373 - May cause damage to organs (respiratory system, Kidney, liver) through prolonged or repeated exposure.

Precautionary Statements (GHS-US/CA)

: P260 - Do not breathe dust.

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves, protective clothing, and eye protection.

P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for

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breathing.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 - Call a POISON CENTER or doctor if you feel unwell.

P314 - Get medical advice/attention if you feel unwell.

P330 - Rinse mouth.

P332+P313 - If skin irritation 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.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Pantoprazole sodium	1H-Benzimidazole, 6-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-, sodium salt (1:1) / Pantoprazole sodium anhydrous	(CAS-No.) 138786-67-1	97.6	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Carc. 2, H351 STOT SE 3, H335 STOT RE 1, H372
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	Acetic acid, (ethylenedinitrilo)tetra-, disodium salt, dihydrate / Glycine, N,N'-1,2-ethanediylbis(N-(carboxymethyl)-, disodium salt, dihydrate (9CI) / Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate / Disodium dihydrate EDTA / Ethylenediaminetetraacetic acid, sodium salt, dihydrate / Ethylenediaminetetraacetic acid (EDTA), disodium salt, dihydrate / Disodium ethylenediamine tetraacetate / Ethylenediaminetetraacetic acid sodium salt dihydrate / Disodium edetate hydrate / Ethylenediaminetetraacetic acid (EDTA), disodium salt, dihydrate / Ethylenediaminetetraacetic acid sodium salt dihydrate / Ethylenediaminetetraacetic acid, disodium, dihydrate / Ethylenediaminetetraacetic acid disodium salt / Disodium ethylenediaminetetraacetate / Sodium edetate hydrate /	(CAS-No.) 6381-92-6	2.4	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 STOT RE 2, H373 Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust

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	Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)			
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 3, H402 Aquatic Chronic 3, H412
Nitrogen	Nitrogen gas / Nitrogen, liquefied / NITROGEN / Nitrogen, compressed / nitrogen	(CAS-No.) 7727-37-9	< 0.1	Simple Asphy Press. Gas (Comp.), H280

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Obtain medical attention if irritation develops or persists. Immediately drench affected area with water for at least 15 minutes.

Eye Contact: Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause respiratory irritation. Causes skin irritation. Causes serious eye irritation. Harmful if swallowed. May cause cancer. Causes damage to organs (Respiratory system, kidneys, liver) through prolonged or repeated exposure.

Inhalation: Irritation of the respiratory tract and the other mucous membranes.

Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Causes damage to organs (Respiratory system, kidneys, liver) through prolonged or repeated exposure. May cause cancer.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Hydrogen Fluoride (HF). Sodium oxides. Sulfur dioxide. Nitrous fumes.

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5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Avoid breathing dust.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: The product is stored under nitrogen. Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Storage temperature: 20 °C - 25°C (68 °F - 77 °F); excursions permitted to 15 °C - 30 °C (59 °F - 86 °F) [see USP Controlled Room Temperature]. Protect from light.

Incompatible Materials: Oxidizers.

7.3. Specific End Use(s)

Pantoprazole Sodium for Injection is a proton pump inhibitor (PPI) for intravenous use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL Ceiling	2 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	2 mg/m ³
USA NIOSH	NIOSH REL (Ceiling)	2 mg/m ³
USA IDLH	IDLH	10 mg/m ³
Alberta	OEL C	2 mg/m ³
British Columbia	OEL C	2 mg/m ³
Manitoba	OEL C	2 mg/m ³
New Brunswick	OEL C	2 mg/m ³

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Newfoundland & Labrador	OEL C	2 mg/m ³
Nova Scotia	OEL C	2 mg/m ³
Nunavut	OEL C	2 mg/m ³
Northwest Territories	OEL C	2 mg/m ³
Ontario	OEL C	2 mg/m ³
Prince Edward Island	OEL C	2 mg/m ³
Québec	Plafond (OEL Ceiling)	2 mg/m ³
Saskatchewan	OEL C	2 mg/m ³
Yukon	OEL C	2 mg/m ³
Nitrogen (7727-37-9)		
USA ACGIH	ACGIH chemical category	Simple asphyxiant See Appendix F: Minimal Oxygen Content

8.2. Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: White to off-white crystalline powder
Odor	: Not available
Odor Threshold	: Not available
pH	: 9.0 – 10.5
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: Not available
Relative Density	: Not available
Specific Gravity	: Not available

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Solubility	: Not available
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Avoid dust formation. Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Oxidizers.
- 10.6. Hazardous Decomposition Products:** Decomposes slowly under the influence of air and light.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Harmful if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

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ATE US/CA (oral)	756.64 mg/kg body weight

Skin Corrosion/Irritation: Causes skin irritation.

Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs (respiratory system) through prolonged or repeated exposure (Inhalation).

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Causes damage to organs (Respiratory system, kidneys, liver) through prolonged or repeated exposure. May cause cancer.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
LD50 Oral Rat	2000 mg/kg
ATE US/CA (dust, mist)	1.50 mg/l/4h
Pantoprazole sodium (138786-67-1)	
LD50 Oral Rat	747 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

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LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Pantoprazole Sodium for Injection, 40 mg	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil

Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Carcinogenicity Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation Health hazard - Acute toxicity (any route of exposure)
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Nitrogen (7727-37-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Sodium hydroxide (1310-73-2)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
Nitrogen (7727-37-9)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	

15.3. Canadian Regulations

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Sodium hydroxide (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List)

Nitrogen (7727-37-9)

Listed on the Canadian DSL (Domestic Substances List)

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 05/13/2021

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Carc. 2	Carcinogenicity Category 2
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Press. Gas (Comp.)	Gases under pressure Compressed gas
Simple Asphy	Simple Asphyxiant
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H280	Contains gas under pressure; may explode if heated
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H372	Causes damage to organs through prolonged or repeated exposure
H373	May cause damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life

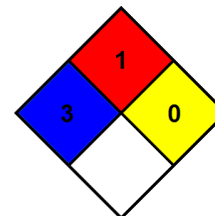
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H412	Harmful to aquatic life with long lasting effects
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- NFPA Health Hazard** : 3 - Materials that, under emergency conditions, can cause serious or permanent injury.
- NFPA Fire Hazard** : 1 - Materials that must be preheated before ignition can occur.
- NFPA Reactivity Hazard** : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

- Health** : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given
* Chronic - Chronic (long-term) health effects may result from repeated overexposure
- Flammability** : 1 Slight Hazard
- Physical** : 0 Minimal Hazard

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.

NA GHS SDS 2015 (Can, US)