### 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 Wheeling 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:

- Signal word (GHS-US): Danger
- Hazard pictograms (GHS-US): GHS07, GHS08
- 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
3.2. Mixture

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

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
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

<table>
<thead>
<tr>
<th>Sodium hydroxide (1310-73-2)</th>
<th>ACGIH</th>
<th>ACGIH Ceiling (mg/m³)</th>
<th>2 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
<td>2 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Pantoprazole Sodium for Injection</th>
<th>747.000 mg/kg body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pantoprazole sodium (138786-67-1)</td>
<td>747 mg/kg</td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>747 mg/kg</td>
</tr>
<tr>
<td>ATE US (oral)</td>
<td>747.000 mg/kg body weight</td>
</tr>
<tr>
<td>Sodium hydroxide (1310-73-2)</td>
<td>1350 mg/kg</td>
</tr>
<tr>
<td>LD50 dermal rabbit</td>
<td>1350.000 mg/kg</td>
</tr>
<tr>
<td>ATE US (dermal)</td>
<td></td>
</tr>
</tbody>
</table>

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) | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |

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 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:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral) Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 3</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 3</td>
</tr>
<tr>
<td>Carc. 1B</td>
<td>Carcinogenicity Category 1B</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Met. Corr. 1</td>
<td>Corrosive to metals Category 1</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation Category 1A</td>
</tr>
<tr>
<td>H290</td>
<td>May be corrosive to metals</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H350</td>
<td>May cause cancer</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
</tbody>
</table>

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.