1. Identification

Product identifier: Propantheline Bromide Tablets USP

Other means of identification:
- 15mg white, film coated tablet, debossed with “54 303” on one side, and plain on the other

Recommended use: Effective as adjunctive therapy in the treatment of peptic ulcer

Recommended restrictions: None known.

Manufacturer/Importer/Supplier/Distributor information:
- Company name: Boehringer Ingelheim Roxane Inc.
- Address: 1809 Wilson Road
  Columbus, Ohio 43228
- Telephone: (614) 276-4000
- Emergency phone number: (614) 276-4000

2. Hazard(s) identification

- Physical hazards: Not classified.
- Health hazards: Not classified.
- OSHA defined hazards: Not classified.

Label elements:
- Hazard symbol: None.
- Signal word: Warning
- Hazard statement: This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement:
- Prevention: Observe good industrial hygiene practices.
- Response: Wash hands after handling.
- Storage: Store at 20 – 25 ºC (68 - 77ºF). Store away from incompatible materials.
- Disposal: Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC): None known.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substances</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Propantheline Bromide</td>
<td></td>
<td>50-34-0</td>
<td>15mg</td>
</tr>
</tbody>
</table>

Composition comments: Refer to Physician's Desk Reference for common components present at <1%

4. First-aid measures

Inhalation: If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

Skin contact: Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact: Rinse with water. Get medical attention if irritation develops and persists.

Ingestion: Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed

May cause varying degrees of drying of salivary secretions as well as decreased sweating. Ophthalmic side effects include blurred vision, mydriasis, cyclopegia and increased ocular tension. Other reported side effects are headache, nervousness, mental confusion, drowsiness, insomnia, nausea, vomiting, constipation and impotence.

Indication of immediate medical attention and special treatment needed

In the event of an overdosage, the following measures should be taken: (1) immediate induction of emesis or lavage of the stomach and (2) injection of physostigmine 0.5 to 2 mg intravenously, and repeated as necessary up to a total of 5 mg, and (3) monitoring of vital signs and managing as necessary.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Use water spray to cool unopened containers.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).

Methods and materials for containment and cleaning up

Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Store at 20 – 25 ºC (68 - 77ºF). Dispense in a tight, light-resistant container as defined in the USP/NF. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dust</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m³</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

US. OSHA Table Z-3 (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dust</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m³</td>
<td>Total dust.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50 mppcf</td>
<td>Total dust.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mppcf</td>
<td>Respirable fraction.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dust</td>
<td>TWA</td>
<td>3 mg/m³</td>
<td>Respirable particles.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td>Inhalable particles.</td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).
Ventilation should be matched to conditions.

**Appropriate engineering controls**

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin protection**

**Hand protection**

For consumer use, no unusual precautions are necessary.

**Other**

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection**

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. Physical and chemical properties

**Appearance**

**Physical state**

Solid.

**Form**

Tablet.

**Color**

White.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)**

Not available.

**Flammability limit - upper (%)**

Not available.

**Explosive limit - lower (%)**

Not available.

**Explosive limit - upper (%)**

Not available.

**Vapor pressure**

Not available.

**Vapor density**

Not available.

**Relative density**

Not available.

**Solubility(ies)**

**Solubility (water)**

Soluble

**Partition coefficient (n-octanol/water)**

Not available.

**Auto-ignition temperature**

Not available.

**Decomposition temperature**

Not available.
10. Stability and reactivity

Reactivity
The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation
Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.

Skin contact
Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate skin.

Eye contact
Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.

Ingestion
Ingestion may cause irritation and malaise.

Symptoms related to the physical, chemical and toxicological characteristics
May cause varying degrees of drying of salivary secretions as well as decreased sweating. Ophthalmic side effects include blurred vision, mydriasis, cyclopegia and increased ocular tension. Other reported side effects are headache, nervousness, mental confusion, drowsiness, insomnia, nausea, vomiting, constipation and impotence.

Information on toxicological effects

Acute toxicity
May be harmful if swallowed in large quantities.

Skin corrosion/irritation
Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation
Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization
Not a respiratory sensitizer.

Skin sensitization
This product is not expected to cause skin sensitization.

Germ cell mutagenicity
No mutagenicity studies have been conducted

Carcinogenicity
Long-term studies in animals have not been conducted to evaluate carcinogenic potential

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

Reproductive toxicity
Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women.

It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman

Specific target organ toxicity - single exposure
Not classified.

Specific target organ toxicity - repeated exposure
Not classified.

Aspiration hazard
Due to the physical form of the product it is not an aspiration hazard.

Further information
See package insert.

12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
Product components are soluble in water and will slowly dissolve and disperse.

Other adverse effects
None.
13. Disposal considerations

Disposal instructions
Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

15. Regulatory information

US federal regulations
This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component’s occupational exposure limits may be surpassed, they can be considered hazardous.


TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.
Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations
US. Massachusetts RTK - Substance List
Not regulated.
US. New Jersey Worker and Community Right-to-Know Act
Not listed.
US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.
US. Rhode Island RTK
Not regulated.
US. California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

* A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 08-May-2015
Revision date -
Version # 01

References
1) Propantheline Bromide Tablets USP, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio.

2) PDR – Physicians Desk Reference.


Disclaimer
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