## Section 1: Identification

### Product identifier

**Product Name**
- Pyridostigmine bromide, Extended Release Tablets

**Product Code**
- NDC 68682-301-30

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

**Recommended use**
- No data available

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

**Manufacturer**
- Valeant Pharmaceuticals International, Inc.
  - 2150 St. Elzear West
  - Laval H7L 4A8
  - Canada
  - valeant.com

**Supplier**
- Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals N. America, LLC
  - 400 Somerset Corporate Blvd.
  - Bridgewater, NJ 08807
  - United States
  - valeant.com

**Telephone (General)**
- 1-800-321-4576

### Emergency telephone number

**Supplier**
- 1-800-535-5053 - US - Infotrac
- +1 352-323-3500 - International - Infotrac

---

## Section 2: Hazard Identification

**UN GHS**

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Classification of the substance or mixture

**UN GHS**
- Acute Toxicity Oral 3

### Label elements

**UN GHS**

**DANGER**

**Hazard statements**
- Toxic if swallowed

**Precautionary statements**

**Prevention**
- Do not handle until all safety precautions have been read and understood.
  - Use personal protective equipment as required.
The exact percentage of composition has been withheld as a trade secret.

**Response**
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

**Storage/Disposal**
- Keep tightly closed. Store at controlled room temperature 25°C (77°F) (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

**Other hazards**
- **UN GHS**
  - No data available

---

**Section 3 - Composition/Information on Ingredients**

**Substances**
- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

**Mixtures**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carnauba Wax</td>
<td>CAS:8015-86-9</td>
<td>20% TO 30%</td>
</tr>
<tr>
<td></td>
<td>EINECS:232-399-4</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>CAS:557-04-0</td>
<td>1% TO 3%</td>
</tr>
<tr>
<td></td>
<td>EINECS:209-150-3</td>
<td></td>
</tr>
<tr>
<td>Pyridostigmine bromide</td>
<td>EINECS:202-929-9</td>
<td>28.75%</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>CAS:7631-86-9</td>
<td>5% TO 10%</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-545-4</td>
<td></td>
</tr>
<tr>
<td>Tribasic calcium phosphate</td>
<td>CAS:7758-87-4</td>
<td>10% TO 20%</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-840-8</td>
<td></td>
</tr>
<tr>
<td>Zein</td>
<td>CAS:9010-66-6</td>
<td>20% TO 30%</td>
</tr>
<tr>
<td></td>
<td>EINECS:232-722-9</td>
<td></td>
</tr>
</tbody>
</table>

Wash thoroughly after handling.

---

**Section 4: First-Aid Measures**

**Description of first aid measures**

**Inhalation**
- Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

**Skin**
- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention.

**Eye**
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get medical attention immediately if symptoms occur.

**Ingestion**
- If swallowed, seek medical advice immediately and show this container or label.
Most important symptoms and effects, both acute and delayed

- As is true of all cholinergic drugs, overdosage of pyridostigmine bromide extended-release tablets may result in cholinergic crisis, a state characterized by increasing muscle weakness which, through involvement of the muscles of respiration, may lead to death.

Indication of any immediate medical attention and special treatment needed

Notes to Physician
- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

Antidotes
- The immediate use of atropine in cholinergic crisis is recommended.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
- Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media
- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- No data available

Hazardous Combustion Products
- No data available.

Advice for firefighters
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures
- Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

Environmental precautions
- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures
- LARGE SPILLS: Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled tablets with water prior to cleaning up to prevent dust cloud.

Section 7 - Handling and Storage

Precautions for safe handling

Handling
- Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage
- Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.
Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

<table>
<thead>
<tr>
<th>Exposure Limits/Guidelines</th>
<th>Result</th>
<th>NIOSH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide (7631-86-9)</td>
<td>TWAs</td>
<td>6 mg/m3 TWA</td>
</tr>
</tbody>
</table>

Exposure controls

Engineering Measures/Controls

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

Hands

- Wear protective gloves when handling bulk product before closed in final packaging.

Skin/Body

- Avoid contact with skin.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Material Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Description</td>
</tr>
<tr>
<td>Physical Form</td>
</tr>
<tr>
<td>Color</td>
</tr>
<tr>
<td>Appearance/Description</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point</td>
</tr>
<tr>
<td>Melting Point</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
</tr>
<tr>
<td>Specific Gravity/Relative Density</td>
</tr>
<tr>
<td>Water Solubility</td>
</tr>
<tr>
<td>Viscosity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volatility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapor Pressure</td>
</tr>
<tr>
<td>Evaporation Rate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flammability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash Point</td>
</tr>
<tr>
<td>UEL</td>
</tr>
<tr>
<td>LEL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octanol/Water Partition coefficient</td>
</tr>
</tbody>
</table>
Section 10: Stability and Reactivity

Reactivity
- Stable under normal temperatures and pressures.

Chemical stability
- Hazardous polymerization will not occur.

Possibility of hazardous reactions
- No data available

Conditions to avoid
- Light, heat and humidity.

Incompatible materials
- Strong oxidizing agents.

Hazardous decomposition products
- When heated to decomposition, toxic fumes of nitrous oxides, sulfur oxides, hydrogen chloride and carbon oxides may be emitted.

Section 11 - Toxicological Information

Information on toxicological effects

<table>
<thead>
<tr>
<th>Components</th>
<th>Pyridostigmine bromide (28.75%) 101-26-8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Toxicity:</td>
<td>Ingestion/Oral-Mouse LD50 • 16 mg/kg; Sense Organs and Special Senses: Eye: Miosis (pupillary constriction); Behavioral: Somnolence (general depressed activity); Lungs, Thorax, or Respiration: Respiratory stimulation; Ingestion/Oral-Rat LD50 • 37500 µg/kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GHS Properties</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory sensitization</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Acute toxicity</td>
<td>UN GHS • Acute Toxicity 3</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>STOT-RE</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>STOT-SE</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
</tbody>
</table>

Potential Health Effects

Inhalation
- **Acute (Immediate)**: Under normal conditions of use, no health effects are expected. Exposure to dust from broken tablets may cause irritation.
- **Chronic (Delayed)**: Repeated and prolonged exposure may cause irritation.
Skin
   Acute (Immediate) • Under normal conditions of use, no health effects are expected.
   Chronic (Delayed) • Repeated and prolonged exposure may cause irritation.

Eye
   Acute (Immediate) • May cause mild eye irritation with direct contact to eye.
   Chronic (Delayed) • Under normal conditions of use, no health effects are expected.

Ingestion
   Acute (Immediate) • Toxic if ingested in excess of prescription dose.
   Chronic (Delayed) • No data available

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>IARC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>Group 3-Not Classifiable</td>
</tr>
</tbody>
</table>

Section 12 - Ecological Information

Toxicity
   • This material has not been tested for environmental effects.

Persistence and degradability
   • No data available

Bioaccumulative potential
   • No data available

Mobility in Soil
   • No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste
   • Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste
   • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

<table>
<thead>
<tr>
<th></th>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>ID8000</td>
<td>Consumer Commodity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDG</td>
<td>NDA</td>
<td>NDA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>UN3249</td>
<td>MEDICINE, SOLID, TOXIC, N.O.S. (PYRIDOSTIGMINE BROMIDE)</td>
<td></td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>ID8000</td>
<td>Consumer Commodity</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Special precautions for user • No data available
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications

No data available

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>Canada NDSL</th>
<th>EU EINECS</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carnauba Wax</td>
<td>8015-86-9</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Silicon dioxide</td>
<td>7631-86-9</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tribasic calcium phosphate</td>
<td>7758-87-4</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Pyridostigmine bromide</td>
<td>101-26-8</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Zein</td>
<td>9010-66-6</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Canada

Labor

Canada - WHMIS - Classifications of Substances
- Magnesium stearate 557-04-0 Not Listed
- Carnauba Wax 8015-86-9 Not Listed
- Tribasic calcium phosphate 7758-87-4 Not Listed
- Pyridostigmine bromide 101-26-8 Not Listed
- Silicon dioxide 7631-86-9 Uncontrolled product according to WHMIS classification criteria
- Zein 9010-66-6 Not Listed

Canada - WHMIS - Ingredient Disclosure List
- Magnesium stearate 557-04-0 Not Listed
- Carnauba Wax 8015-86-9 Not Listed
- Tribasic calcium phosphate 7758-87-4 Not Listed
- Pyridostigmine bromide 101-26-8 Not Listed
- Silicon dioxide 7631-86-9 1 %
- Zein 9010-66-6 Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List
- Magnesium stearate 557-04-0 Not Listed
- Carnauba Wax 8015-86-9 Not Listed
- Tribasic calcium phosphate 7758-87-4 Not Listed
- Pyridostigmine bromide 101-26-8 Not Listed
- Silicon dioxide 7631-86-9 Not Listed
- Zein 9010-66-6 Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity
### Section 16 - Other Information

#### U.S. - California - Proposition 65 - Reproductive Toxicity - Female
- Magnesium stearate 557-04-0 Not Listed
- Carnauba Wax 8015-86-9 Not Listed
- Tribasic calcium phosphate 7758-87-4 Not Listed
- Pyridostigmine bromide 101-26-8 Not Listed
- Silicon dioxide 7631-86-9 Not Listed
- Zein 9010-66-6 Not Listed

#### U.S. - California - Proposition 65 - Reproductive Toxicity - Male
- Magnesium stearate 557-04-0 Not Listed
- Carnauba Wax 8015-86-9 Not Listed
- Tribasic calcium phosphate 7758-87-4 Not Listed
- Pyridostigmine bromide 101-26-8 Not Listed
- Silicon dioxide 7631-86-9 Not Listed
- Zein 9010-66-6 Not Listed

#### Revision Date
- 05/November/2015

#### Last Revision Date
- 05/November/2015

#### Preparation Date
- 05/November/2015

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