Safety Data Sheet

Section 1: Identification

Product identifier

Product Name
• Cardizem® LA Tablets (120 mg-420 mg)

Synonyms
• Diltiazem hydrochloride

Product Code
• NDC 00074-3045-30; NDC 00074-3045-90; NDC 00074-3061-30; NDC 00074-3061-90; NDC 00074-3062-30; NDC 00074-3062-90; NDC 00074-3063-30; NDC 00074-3063-90; NDC 00074-3064-30; NDC 00074-3064-90; NDC 00074-3069-30; NDC 00074-3069-90; NDC 00187-2045-30; NDC 00187-2045-90; NDC 00187-2046-30; NDC 00187-2046-90; NDC 00187-2047-30; NDC 00187-2047-90; NDC 00187-2048-30; NDC 00187-2048-90; NDC 00187-2049-30; NDC 00187-2049-90; NDC 00187-2050-30; NDC 00187-2050-90

Product Description
• Prescription pharmaceutical product.

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

Recommended use
• CARDIZEM LA is a nondihydropyridine calcium channel blocker indicated for treatment of hypertension.

Restrictions on use
• Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer
• Valeant Pharmaceuticals International, Inc.
  100 LifeSciences Parkway
  Steinbach R5G 1Z7
  United States
  valeant.com

Telephone (General) • 1-800-321-4576

Supplier
• Valeant Pharmaceuticals North America, LLC
  Bridgewater, NJ 08807
  United States
  valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Supplier
• 1-800-535-5053

Supplier
• +1 352-323-3500

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

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 4
- Reproductive Toxicity 2
- Specific Target Organ Toxicity Single Exposure 2

Label elements

UN GHS

WARNING

Hazard statements

- Harmful if swallowed
  May cause damage to organs (cardiovascular system).
  Suspected of damaging fertility or the unborn child.
- May cause damage to organs.

Precautionary statements

Prevention

- Do not handle until all safety precautions have been read and understood.
- Avoid breathing dust, fume, gas, mist, vapours and/or spray.
- Use personal protective equipment as required.
- Wash thoroughly after handling.

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

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

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>
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</thead>
<tbody>
<tr>
<td>Carnauba Wax</td>
<td>CAS:8015-86-9</td>
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<tr>
<td></td>
<td>EINECS:232-399-4</td>
<td></td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>CAS:7631-86-9</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EINECS:231-545-4</td>
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<tr>
<td>Croscarmellose sodium</td>
<td>CAS:74811-65-7</td>
<td>N/A</td>
</tr>
<tr>
<td>Diltiazem hydrochloride</td>
<td>CAS:33286-22-5</td>
<td>33.84%</td>
</tr>
<tr>
<td></td>
<td>EINECS:251-443-3</td>
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<tr>
<td>Hydrogenated vegetable oil, Type 1</td>
<td>CAS:8016-70-4</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EINECS:232-410-2</td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>CAS:9004-65-3</td>
<td>N/A</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>CAS:557-04-0</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EINECS:209-150-3</td>
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</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>CAS:9004-34-6</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EINECS:232-674-9</td>
<td></td>
</tr>
</tbody>
</table>
Microcrystalline wax | CAS: 63231-60-7 | EINECS: 264-039-1 | N/A
Opadry II White | NDA | N/A
P(EA/MMA) Polymer | CAS: 9010-88-2 | N/A
Polysorbate 80 | CAS: 9005-65-6 | N/A
Povidone K30 | CAS: 9003-39-8 | N/A
Pregelatinized starch | CAS: 9005-84-9 | EINECS: 232-686-4 | N/A
Simethicone | CAS: 8050-81-5 | N/A
Sodium Starch Gylocate | CAS: 9063-38-1 | N/A
Sucrose stearate | CAS: 25168-73-4 | EINECS: 246-705-9 | N/A
Talc | CAS: 14807-96-6 | EINECS: 238-877-9 | N/A
Titanium dioxide | CAS: 13463-67-7 | EINECS: 236-675-5 | N/A

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

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  
• No specific treatment is necessary since this material is not hazardous by ingestion when used in accordance with product literature. If quantities exceeding the recommended intake are accidentally ingested, get medical attention immediately.

Most important symptoms and effects, both acute and delayed  
• Events observed following diltiazem overdose included bradycardia, hypotension, heart block, and cardiac failure.

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  
• In the event of overdose or exaggerated response, institute appropriate supportive measures and gastrointestinal decontamination. Diltiazem does not appear to be removed by peritoneal or hemodialysis. Limited data suggest that plasmapheresis or charcoal hemoperfusion may hasten diltiazem elimination following overdose. Based on the known pharmacological effects of diltiazem and/or reported clinical experiences, the following measures may be considered: Bradycardia: Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously. High-degree AV Block: Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing. Cardiac Failure: Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics. Hypotension: Use vasopressors (e.g., dopamine or norepinephrine). Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.
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. Protect from light.

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>Result</th>
<th>ACGIH</th>
<th>Canada Quebec</th>
<th>NIOSH</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 mg/m3 TWAEV</td>
<td></td>
</tr>
<tr>
<td>Material Description</td>
<td>Physical Form</td>
<td>Appearance/Description</td>
<td>General Properties</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------</td>
<td>------------------------</td>
<td>-------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong> (13463-67-7)</td>
<td>TWAs</td>
<td>10 mg/m3 TWA (containing no Asbestos and &lt;1% Crystalline silica, total dust)</td>
<td>White, oval tablet with &quot;B&quot; on one side and content (mg) on the other side.</td>
<td></td>
</tr>
<tr>
<td><strong>Talc</strong> (14807-96-6)</td>
<td>TWAs</td>
<td>2 mg/m3 TWA (particulate matter containing no asbestos and &lt;1% crystalline silica, respirable fraction)</td>
<td>187 to 210 C (368.6 to 410 F)</td>
<td></td>
</tr>
<tr>
<td><strong>Colloidal silicon dioxide</strong> (7631-86-9)</td>
<td>TWAs</td>
<td>Not established</td>
<td>Not relevant</td>
<td></td>
</tr>
<tr>
<td><strong>Microcrystalline cellulose</strong> (9004-34-6)</td>
<td>TWAs</td>
<td>10 mg/m3 TWA (containing no Asbestos and &lt;1% Crystalline silica, total dust)</td>
<td>Not relevant</td>
<td></td>
</tr>
</tbody>
</table>

**Exposure Control Notations**

ACGIH

• Talc (14807-96-6): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers))
• Titanium dioxide (13463-67-7): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)

**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>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>General Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Form</strong></td>
<td>Solid</td>
<td>White</td>
<td>Melting Point/Freezing Point</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>White</td>
<td>Odor</td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>Taste</strong></td>
<td>Bitter</td>
<td></td>
<td>Water Solubility</td>
</tr>
<tr>
<td><strong>General Properties</strong></td>
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<td></td>
<td>Soluble</td>
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<tr>
<td><strong>Boiling Point</strong></td>
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<td>187 to 210 C (368.6 to 410 F)</td>
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<td><strong>Decomposition Temperature</strong></td>
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<td>Not relevant</td>
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<td><strong>Specific Gravity/Relative Density</strong></td>
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<td>Soluble</td>
</tr>
<tr>
<td><strong>Solvent Solubility</strong></td>
<td>Chloroform; Methanol</td>
<td></td>
<td>Not relevant</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>Acute Toxicity: Ingestion/Oral-Mouse LD50 • 508 mg/kg; Ingestion/Oral-Rat LD50 • 560 mg/kg; Behavioral:Antipsychotic</th>
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</thead>
<tbody>
<tr>
<td>Diltiazem hydrochloride</td>
<td>33286-22-5</td>
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GHS Properties

<table>
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<tr>
<th>Classification</th>
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<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
</tr>
</tbody>
</table>

Serious eye damage/Irritation

<table>
<thead>
<tr>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
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</table>

Acute toxicity

<table>
<thead>
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<th>Classification</th>
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</thead>
<tbody>
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<td>UN GHS • Acute Toxicity - Oral 4</td>
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Aspiration Hazard

<table>
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<tr>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
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</tbody>
</table>

Carcinogenicity

<table>
<thead>
<tr>
<th>Classification</th>
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<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
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</table>

Skin corrosion/Irritation

<table>
<thead>
<tr>
<th>Classification</th>
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</thead>
<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
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</table>

Skin sensitization

<table>
<thead>
<tr>
<th>Classification</th>
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<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
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STOT-RE

<table>
<thead>
<tr>
<th>Classification</th>
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<tbody>
<tr>
<td>UN GHS • Classification criteria not met</td>
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STOT-SE

<table>
<thead>
<tr>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN GHS • Specific Target Organ Toxicity Single Exposure 2</td>
</tr>
</tbody>
</table>
Toxicity for Reproduction  | UN GHS • Toxic to Reproduction 2
Germ Cell Mutagenicity  | UN GHS • Classification criteria not met

### 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)**
- May affect the heart and/or cardiovascular system. Symptoms may include hypotension, bradycardia, heart block and cardiac failure. Toxic if ingested in excess of prescription dose.

**Chronic (Delayed)**
- No data available

### Carcinogenic Effects

<table>
<thead>
<tr>
<th>CAS</th>
<th>IARC</th>
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<tbody>
<tr>
<td>Polysorbate 80</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>Group 2B-Possible Carcinogen</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>Group 3-Not Classifiable</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>Group 3-Not Classifiable</td>
</tr>
<tr>
<td>Povidone K30</td>
<td>9003-39-8</td>
<td>Group 3-Not Classifiable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evidence of Carcinogenicity</td>
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<td>Not Listed</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Reproductive Effects

- Pregnancy category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times (on a mg/kg basis) the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was an increased incidence of stillbirths at doses of 20 times the human dose or greater. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels.

### 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>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>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>TDG</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</td>
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</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>EU EINECS</th>
<th>EU ELNICS</th>
<th>TSCA</th>
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</thead>
<tbody>
<tr>
<td>Diltiazem hydrochloride</td>
<td>33286-22-5</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<td>Hydroxypropyl methylcellulose</td>
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<td>No</td>
<td>No</td>
<td>Yes</td>
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<td>Microcrystalline wax</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>P(EA/MMA) Polymer</td>
<td>9010-88-2</td>
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<td>No</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Hydrogenated vegetable oil, Type 1</td>
<td>8016-70-4</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Povidone K30</td>
<td>9003-39-8</td>
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<td>No</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Sodium Starch Gylcate</td>
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<td>No</td>
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<td>Ingredient</td>
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<td>Canada WHMIS Classification of Substances</td>
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<td>----------------</td>
<td>----------------</td>
<td>------------------------------------------</td>
<td></td>
<td></td>
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<tr>
<td>Pregelatinized starch</td>
<td>9005-84-9</td>
<td>Yes</td>
<td>Povidone K30 uncontrolled product according to WHMIS classification criteria (listed under Providone)</td>
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<td>Magnesium stearate</td>
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<td>Microcrystalline wax unlisted</td>
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<td>Sucrose stearate</td>
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<td>Yes</td>
<td>Hydroxypropyl methylcellulose unlisted</td>
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<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>Yes</td>
<td>P(EA/MMA) Polymer unlisted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>Yes</td>
<td>Magnesium stearate unlisted</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Microcrystalline cellulose unlisted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pregelatinized starch unlisted</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Talc D2A</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Titanium dioxide D2A (In certain cases, this classification does not apply. For more information, consult the section Substance Specific Issues - Titanium dioxide, mixture containing on Health Canada's WHMIS Division website.)</td>
<td></td>
<td></td>
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### Canada - WHMIS - Ingredient Disclosure List
- Povidone K30 9003-39-8 Not Listed
- Microcrystalline wax 63231-60-7 Not Listed
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- P(EA/MMA) Polymer 9010-88-2 Not Listed
- Magnesium stearate 557-04-0 Not Listed
- Microcrystalline cellulose 9004-34-6 Not Listed
- Pregelatinized starch 9005-84-9 Not Listed
- Colloidal silicon dioxide 7631-86-9 Not Listed
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<th>List Status</th>
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<td>Talc</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
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</tr>
<tr>
<td>Diltiazem hydrochloride</td>
<td>33286-22-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Hydrogenated vegetable oil, Type 1</td>
<td>8016-70-4</td>
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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
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<tr>
<td>Sodium Starch Gylocate</td>
<td>9063-38-1</td>
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</tr>
<tr>
<td>Sucrose stearate</td>
<td>25168-73-4</td>
<td>Not Listed</td>
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<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
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</table>

### United States - California

#### Environment

**U.S. - California - Proposition 65 - Carcinogens List**

- Povidone K30 9003-39-8 Not Listed
- Microcrystalline wax 63231-60-7 Not Listed
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- P(EA/MMA) Polymer 9010-88-2 Not Listed
- Magnesium stearate 557-04-0 Not Listed
- Microcrystalline cellulose 9004-34-6 Not Listed
- Pregelatinized starch 9005-84-9 Not Listed
- Talc 14807-96-6 Not Listed
- Titanium dioxide 13463-67-7 Not Listed
- Diltiazem hydrochloride 33286-22-5 Not Listed
- Hydrogenated vegetable oil, Type 1 8016-70-4 Not Listed
- Croscarmellose sodium 74811-65-7 Not Listed
- Sodium Starch Gylocate 9063-38-1 Not Listed
- Sucrose stearate 25168-73-4 Not Listed
- Colloidal silicon dioxide 7631-86-9 Not Listed

**U.S. - California - Proposition 65 - Developmental Toxicity**

- Povidone K30 9003-39-8 Not Listed
- Microcrystalline wax 63231-60-7 Not Listed
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- P(EA/MMA) Polymer 9010-88-2 Not Listed
- Magnesium stearate 557-04-0 Not Listed
- Microcrystalline cellulose 9004-34-6 Not Listed
- Pregelatinized starch 9005-84-9 Not Listed
- Talc 14807-96-6 Not Listed
- Titanium dioxide 13463-67-7 Not Listed
devontational toxicity, initial date 2/27/01

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**

- Povidone K30 9003-39-8 Not Listed
- Microcrystalline wax 63231-60-7 Not Listed
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- P(EA/MMA) Polymer 9010-88-2 Not Listed
- Magnesium stearate 557-04-0 Not Listed
• Microcrystalline cellulose 9004-34-6 Not Listed
• Pregelatinized starch 9005-84-9 Not Listed
• Talc 14807-96-6 Not Listed
• Titanium dioxide 13463-67-7 Not Listed
• Diltiazem hydrochloride 33286-22-5 Not Listed
• Hydrogenated vegetable oil, Type 1 8016-70-4 Not Listed
• Croscarmellose sodium 74811-65-7 Not Listed
• Sodium Starch Gylocate 9063-38-1 Not Listed
• Sucrose stearate 25168-73-4 Not Listed
• Colloidal silicon dioxide 7631-86-9 Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male
• Povidone K30 9003-39-8 Not Listed
• Microcrystalline wax 63231-60-7 Not Listed
• Hydroxypropyl methylcellulose 9004-65-3 Not Listed
• P(EA/MMA) Polymer 9010-88-2 Not Listed
• Magnesium stearate 557-04-0 Not Listed
• Microcrystalline cellulose 9004-34-6 Not Listed
• Pregelatinized starch 9005-84-9 Not Listed
• Talc 14807-96-6 Not Listed
• Titanium dioxide 13463-67-7 Not Listed
• Diltiazem hydrochloride 33286-22-5 Not Listed
• Hydrogenated vegetable oil, Type 1 8016-70-4 Not Listed
• Croscarmellose sodium 74811-65-7 Not Listed
• Sodium Starch Gylocate 9063-38-1 Not Listed
• Sucrose stearate 25168-73-4 Not Listed
• Colloidal silicon dioxide 7631-86-9 Not Listed

Section 16 - Other Information

Revision Date 21/September/2015
Last Revision Date 21/September/2015
Preparation Date 21/September/2015
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