Section 1: Identification

Product identifier

Product Name: NIFEdipine extended-release tablets (Nifediac CC)
Product Code: NDC 68682-105-10; NDC 68682-105-30; NDC 68682-106-10; NDC 68682-106-30; NDC 68682-107-10

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

Recommended use: Nifedipine extended release tablets are 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
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
Supplier: +1 352-323-3500 - International - Infotrac

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 Revision 3
According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

Classification of the substance or mixture

UN GHS
- Acute Toxicity Oral 4
- Reproductive Toxicity 2
- Specific Target Organ Toxicity Single Exposure 1
- Skin Irritation 2
- Eye Irritation 2A
- Effects on or via Lactation

Label elements

UN GHS
DANGER

Hazard statements • Harmful if swallowed
Causes skin irritation
Causes serious eye irritation
Suspected of damaging fertility or the unborn child.
Causes damage to organs.
May cause harm to breast-fed children

Precautionary statements

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

Response • IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.
IF ON SKIN: Wash with plenty of soap and water.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.

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

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>
<th>Classifications According to Regulation/Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nifedipine</td>
<td>CAS:21829-25-4 EINECS:244-598-3</td>
<td>9% TO 30%</td>
<td>UN GHS Revision 3: NDA</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>CAS:9004-34-6 EINECS:232-674-9</td>
<td>N/A</td>
<td>UN GHS Revision 3: Skin Irrit. 2; Eye Irrit. 2A</td>
</tr>
<tr>
<td>Ethylcellulose</td>
<td>CAS:9004-57-3</td>
<td>N/A</td>
<td>UN GHS Revision 3: NDA</td>
</tr>
<tr>
<td>Hydroxyethyl cellulose</td>
<td>CAS:9004-62-0</td>
<td>N/A</td>
<td>UN GHS Revision 3: Skin Irrit. 2; Eye Irrit. 2A</td>
</tr>
<tr>
<td>Titanium dioxide*</td>
<td>CAS:13463-67-7 EINECS:236-675-5</td>
<td>N/A</td>
<td>UN GHS Revision 3: STOT RE 2; Carc. 2</td>
</tr>
</tbody>
</table>
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
- IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Eye
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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
- Events observed following overdose included hypotension, heart rhythm disturbances, loss of consciousness, 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.

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
- No data available.
Products
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
• Minimize dust generation and accumulation. Use good safety and industrial hygiene practices. Avoid breaking capsules.

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></th>
<th>Result</th>
<th>ACGIH</th>
<th>Canada Quebec</th>
<th>NIOSH</th>
<th>OSHA</th>
<th>Other Agency Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>TWAs</td>
<td>Not established</td>
<td>Not established</td>
<td>Not established</td>
<td>Not established</td>
<td>10 mg/m3 TWA (MW&gt;200, aerosol)</td>
</tr>
<tr>
<td>#600 * (25322-68-3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talc* (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>3 mg/m3 TWAEV (respirable dust)</td>
<td>2 mg/m3 TWA (containing no Asbestos and &lt;1% Quartz, respirable dust)</td>
<td>Not established</td>
<td>Not established</td>
</tr>
<tr>
<td>Titanium dioxide* (13463-67-7)</td>
<td>TWAs</td>
<td>10 mg/m3 TWA</td>
<td>10 mg/m3 TWAEV (containing no Asbestos and &lt;1% Crystalline silica, total)</td>
<td>Not established</td>
<td>15 mg/m3 TWA (total dust)</td>
<td>Not established</td>
</tr>
</tbody>
</table>
Microcrystalline cellulose (9004-34-6)  | TWAs  | 10 mg/m³ TWA  | Microcrystalline cellulose (9004-34-6)  | TWAs  | 10 mg/m³ TWA  | Microcrystalline cellulose (9004-34-6)  | TWAs  | 10 mg/m³ TWA  | Microcrystalline cellulose (9004-34-6)  | TWAs  | 10 mg/m³ TWA  |

- 10 mg/m³ TWA (total dust; 5 mg/m³ TWA (respirable dust))
- Not established

**Exposure Control Notations**

**ACGIH**

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

**Exposure Limits Supplemental**

**OSHA**

- Talc* (14807-96-6): Mineral Dusts: (20 mppcf TWA (if 1% Quartz or more, use Quartz limit))

**ACGIH**

- Microcrystalline cellulose (9004-34-6): TLV Basis - Critical Effects: (upper respiratory tract irritation)
- Titanium dioxide* (13463-67-7): TLV Basis - Critical Effects: (lower respiratory tract irritation)
- Talc* (14807-96-6): TLV Basis - Critical Effects: (pulmonary fibrosis (containing no asbestos fibers); pulmonary function (containing no asbestos fibers))

**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>Color</th>
<th>Appearance/Description</th>
<th>pH</th>
<th>Water Solubility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Form</strong></td>
<td>Solid</td>
<td>Yellow</td>
<td>Odor</td>
<td></td>
<td>Insoluble</td>
</tr>
<tr>
<td><strong>General Properties</strong></td>
<td>No data available</td>
<td>No data available</td>
<td>Melting Point/Freezing Point</td>
<td>172 to 174 °C (341.6 to 345.2 °F)</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>No data available</td>
<td>Melting Point/Freezing Point</td>
<td>172 to 174 °C (341.6 to 345.2 °F)</td>
<td>Not relevant</td>
<td></td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>No data available</td>
<td>pH</td>
<td>Not relevant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Gravity/Relative Density</td>
<td>Not relevant</td>
<td>Water Solubility</td>
<td>Insoluble</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not relevant</td>
<td>Water Solubility</td>
<td>Insoluble</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Vapor Pressure**
  - Not relevant

- **Evaporation Rate**
  - Not relevant
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

- Nitric oxides and carbon monoxides.

Section 11 - Toxicological Information

Information on toxicological effects

<table>
<thead>
<tr>
<th>Components</th>
<th>Nifedipine (9% TO 30%)</th>
<th>Acute Toxicity: Ingestion/Oral-Rat LD50 • 1022 mg/kg; Behavioral:Changes in motor activity (specific assay); Lungs, Thorax, or Respiration:Dyspnea; Lungs, Thorax, or Respiration:Respiratory stimulation; Reproductive: Ingestion/Oral-Rat TDLo • 10 mg/kg (21D preg); Reproductive Effects:Specific Developmental Abnormalities:Cardiovascular (circulatory) system; Ingestion/Oral-Rat TDLo • 40 mg/kg (14D preg); Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system</th>
</tr>
</thead>
</table>

GHS Properties

<table>
<thead>
<tr>
<th>Classification</th>
<th>GHS Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>UN GHS 3 • Acute Toxicity - Oral 4</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
<td>UN GHS 3 • Skin Irritation 2</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
<td>UN GHS 3 • Eye Irritation 2A</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>UN GHS 3 • Classification criteria not met</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>UN GHS 3 • Classification criteria not met</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
<td>UN GHS 3 • Classification criteria not met</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>UN GHS 3 • Classification criteria not met</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>UN GHS 3 • Classification criteria not met</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
<td>UN GHS 3 • Additional category for effects on or via lactation; Toxic to Reproduction 2</td>
</tr>
<tr>
<td>STOT-SE</td>
<td>UN GHS 3 • Specific Target Organ Toxicity Single Exposure 1</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 capsules may cause irritation.
- **Chronic (Delayed)**: Repeated and prolonged exposure may cause irritation.

Skin
- **Acute (Immediate)**: May cause skin irritation.
- **Chronic (Delayed)**: Repeated and prolonged exposure may cause sensitization.

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. May affect the heart and/or cardiovascular system. Symptoms may include hypotension, heart rhythm disturbances and cardiac failure.
- **Chronic (Delayed)**: No data available

Carcinogenic Effects

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS</th>
<th>IARC</th>
<th>NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc*</td>
<td>14807-96-6</td>
<td>Group 3-Not Classifiable</td>
<td>Evidence of Carcinogenicity</td>
</tr>
<tr>
<td>Titanium dioxide*</td>
<td>13463-67-7</td>
<td>Group 2B-Possible Carcinogen</td>
<td>Evidence of Carcinogenicity</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>112945-52-5</td>
<td>Group 3-Not Classifiable</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Reproductive Effects
- There are no adequate and well-controlled studies in humans. In rodents, rabbits, and monkeys, nifedipine has been shown to have a variety of embryotoxic, placentotoxic, and fetotoxic effects. Nifedipine is excreted in human milk.

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 Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>TDG</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</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>EU EINECS</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amino methacrylate copolymer</td>
<td>25086-15-1</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>21829-25-4</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hydroxyethylcellulose</td>
<td>9004-62-0</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Ethylcellulose</td>
<td>9004-57-3</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Iron oxide Yellow</td>
<td>51274-00-1</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Polyethylene glycol #600 *</td>
<td>25322-68-3</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>112945-52-5</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Talc*</td>
<td>14807-96-6</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Titanium dioxide*</td>
<td>13463-67-7</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Canada

Labor

Canada - WHMIS - Classifications of Substances

Uncontrolled product
- **Hydroxypropyl methylcellulose** 9004-65-3 according to WHMIS classification criteria
- **Magnesium stearate** 557-04-0 Not Listed
- **Ethylcellulose** 9004-57-3 according to WHMIS classification criteria
- **Microcrystalline cellulose** 9004-34-6 according to WHMIS classification criteria (including microcrystalline and paper fibers)
- **Talc** 14807-96-6 D2A
- **Titanium dioxide** 13463-67-7 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.)
- **Sodium lauryl sulfate** 151-21-3 D2B
- **Hydroxyethyl cellulose** 9004-62-0 Uncontrolled product according to WHMIS classification criteria
- **Amino methacrylate copolymer** 25086-15-1 Not Listed
- **Lactose** 63-42-3 Not Listed according to WHMIS classification criteria
- **Colloidal silicon dioxide** 112945-52-5 Not Listed
- **Nifedipine** 21829-25-4 Not Listed
- **Polyethylene glycol #600** 25322-68-3 Not Listed
- **Iron oxide Yellow** 51274-00-1 Not Listed according to WHMIS classification criteria

**Canada - WHMIS - Ingredient Disclosure List**
- **Hydroxypropyl methylcellulose** 9004-65-3 Not Listed
- **Magnesium stearate** 557-04-0 Not Listed
- **Ethylcellulose** 9004-57-3 Not Listed
- **Microcrystalline cellulose** 9004-34-6 Not Listed
- **Talc** 14807-96-6 Not Listed
- **Titanium dioxide** 13463-67-7 Not Listed
- **Sodium lauryl sulfate** 151-21-3 1%
- **Hydroxyethyl cellulose** 9004-62-0 Not Listed
- **Amino methacrylate copolymer** 25086-15-1 Not Listed
- **Lactose** 63-42-3 Not Listed
- **Colloidal silicon dioxide** 112945-52-5 Not Listed
- **Nifedipine** 21829-25-4 Not Listed
- **Polyethylene glycol #600** 25322-68-3 Not Listed
- **Iron oxide Yellow** 51274-00-1 Not Listed

**United States - California**

**Environment**

**U.S. - California - Proposition 65 - Carcinogens List**
- **Hydroxypropyl methylcellulose** 9004-65-3 Not Listed
- **Magnesium stearate** 557-04-0 Not Listed
- Ethylcellulose 9004-57-3 Not Listed
- Amylose 9004-34-6 Not Listed
- Talc* 14807-96-6 Not Listed, carcinogen, 9/2/2011, (airborne, unbound particles of respirable size)
- Titanium dioxide* 13463-67-7 Not Listed
- Sodium lauryl sulfate 151-21-3 Not Listed
- Hydroxyethyl cellulose 9004-65-3 Not Listed
- Amino methacrylate copolymer 25086-15-1 Not Listed
- Lactose 63-42-3 Not Listed
- Colloidal silicon dioxide 112945-52-5 Not Listed
- Nifedipine 21829-25-4 Not Listed
- Polyethylene glycol #600 * 25322-68-3 Not Listed
- Iron oxide Yellow 51274-00-1 Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- Magnesium stearate 557-04-0 Not Listed
- Ethylcellulose 9004-57-3 Not Listed
- Microcrystalline cellulose 9004-34-6 Not Listed
- Talc* 14807-96-6 Not Listed
- Titanium dioxide* 13463-67-7 Not Listed
- Sodium lauryl sulfate 151-21-3 Not Listed
- Hydroxyethyl cellulose 9004-62-0 Not Listed
- Amino methacrylate copolymer 25086-15-1 Not Listed
- Lactose 63-42-3 Not Listed
- Colloidal silicon dioxide 112945-52-5 Not Listed
devmental toxicity, 1/29/1999
- Nifedipine 21829-25-4 Not Listed
- Polyethylene glycol #600 * 25322-68-3 Not Listed
- Iron oxide Yellow 51274-00-1 Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- Magnesium stearate 557-04-0 Not Listed
- Ethylcellulose 9004-57-3 Not Listed
- Microcrystalline cellulose 9004-34-6 Not Listed
- Talc* 14807-96-6 Not Listed
- Titanium dioxide* 13463-67-7 Not Listed
- Sodium lauryl sulfate 151-21-3 Not Listed
- Hydroxyethyl cellulose 9004-62-0 Not Listed
- Amino methacrylate copolymer 25086-15-1 Not Listed
- Lactose 63-42-3 Not Listed
- Colloidal silicon dioxide 112945-52-5 Not Listed
female reproductive toxicity, 1/29/99
- Nifedipine 21829-25-4 Not Listed
- Polyethylene glycol #600 * 25322-68-3 Not Listed
- Iron oxide Yellow 51274-00-1 Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male
- Hydroxypropyl methylcellulose 9004-65-3 Not Listed
- Magnesium stearate 557-04-0 Not Listed
- Ethylcellulose 9004-57-3 Not Listed
- Microcrystalline cellulose 9004-34-6 Not Listed
- Talc* 14807-96-6 Not Listed
- Titanium dioxide*
- Sodium lauryl sulfate
- Hydroxyethyl cellulose
- Amino methacrylate copolymer
- Lactose
- Colloidal silicon dioxide
- Nifedipine
- Polyethylene glycol #600 *
- Iron oxide Yellow

Section 16 - Other Information

Revision Date: 07/October/2016
Last Revision Date: 08/March/2016
Preparation Date: 08/March/2016

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