Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • Enalapril maleate tablets (2.5 mg - 20 mg)
Product Description • Prescription pharmaceutical product.

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

Recommended use • Enalapril maleate is 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
According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Specific Target Organ Toxicity Single Exposure 2
Reproductive Toxicity 1
Acute Toxicity Oral 5

Label elements

UN GHS

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

**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

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### 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>Corn starch</td>
<td>CAS:9005-25-8, EINECS:232-679-6</td>
<td>N/A</td>
</tr>
<tr>
<td>Enalapril maleate</td>
<td>CAS:76095-16-4, EINECS:278-375-7</td>
<td>2.2% TO 9.9%</td>
</tr>
<tr>
<td>Ferric oxide red</td>
<td>CAS:1309-37-1, EINECS:215-168-2</td>
<td>N/A</td>
</tr>
<tr>
<td>Ferric oxide yellow</td>
<td>CAS:51274-00-1, EINECS:257-098-5</td>
<td>N/A</td>
</tr>
<tr>
<td>Lactose</td>
<td>CAS:63-42-3</td>
<td>N/A</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>CAS:557-04-0, EINECS:209-150-3</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>CAS:144-55-8, EINECS:205-633-8</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*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 use,
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**
- The most likely manifestation of overdosage would be hypotension.

**Indication of any immediate medical attention and special treatment needed**
- The usual treatment for hypotension would be intravenous infusion of normal saline solution. Enalapril may be removed from general circulation by hemodialysis.

### 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>Exposure Limits/Guidelines</th>
<th>Result</th>
<th>ACGIH</th>
<th>Canada Quebec</th>
<th>NIOSH</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferric oxide red (1309-37-1)</td>
<td>TWAs</td>
<td>5 mg/m3 TWA (respirable fraction)</td>
<td>5 mg/m3 TWAEV (dust and fume, as Fe); 10 mg/m3 TWAEV (containing no Asbestos and &lt;1% Crystalline silica, regulated under Rouge, total dust)</td>
<td>5 mg/m3 TWA (dust and fume, as Fe)</td>
<td>10 mg/m3 TWA (fume); 15 mg/m3 TWA (total dust, listed under Rouge); 5 mg/m3 TWA (respirable fraction, listed under Rouge)</td>
</tr>
<tr>
<td>Corn starch (9005-25-8)</td>
<td>TWAs</td>
<td>10 mg/m3 TWA</td>
<td>10 mg/m3 TWAEV (containing no Asbestos and &lt;1% Crystalline silica, total dust)</td>
<td>10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)</td>
<td>15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)</td>
</tr>
</tbody>
</table>

Exposure Control Notations
ACGIH
- Ferric oxide red (1309-37-1): Carcinogens: (A4 - Not Classifiable as a Human Carcinogen) | Carcinogens: (A4 - Not Classifiable as a Human Carcinogen)
- Corn starch (9005-25-8): 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
- Handle in accordance with good industrial hygiene and safety practice. Wash.
### Section 9 - Physical and Chemical Properties

#### Information on Physical and Chemical Properties

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

#### General Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Boiling Point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition Temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Melting Point/Freezing Point</strong></td>
<td>143 to 144.5 °C (289.4 to 292.1 °F)</td>
</tr>
<tr>
<td><strong>Specific Gravity/Relative Density</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>Solvent Solubility</strong></td>
<td>Alcohol; Dimethylformamide; Methyl alcohol</td>
</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

#### Flammability

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>UEL</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>LEL</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>Autoignition</strong></td>
<td>Not relevant</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

#### Environmental

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Octanol/Water Partition coefficient</strong></td>
<td>No data available</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

- Excessive heat or moisture.

#### Incompatible materials

- Strong oxidizing agents.

#### Hazardous decomposition products

- Nitrous oxides. Irritating and/or toxic fumes or gases.
Section 11 - Toxicological Information

Information on toxicological effects

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Enalapril maleate (2.2% TO 9.9%)</td>
<td></td>
</tr>
<tr>
<td>76095-16-4</td>
<td></td>
</tr>
<tr>
<td><strong>Acute Toxicity:</strong> Ingestion/Oral-Mouse LD50 • 3507 mg/kg; Behavioral: Convulsions or effect on seizure threshold; Behavioral: Ataxia; Lungs, Thorax, or Respiration: Respiratory depression</td>
<td></td>
</tr>
</tbody>
</table>

GHS Properties                                      Classification
Respiratory sensitization                       UN GHS • Classification criteria not met
Serious eye damage/Irritation                    UN GHS • Classification criteria not met
Acute toxicity                                    UN GHS • Acute Toxicity - Oral 5
Aspiration Hazard                                UN GHS • Classification criteria not met
Carcinogenicity                                  UN GHS • Classification criteria not met
Skin corrosion/Irritation                        UN GHS • Classification criteria not met
Skin sensitization                               UN GHS • Classification criteria not met
STOT-RE                                         UN GHS • Classification criteria not met
STOT-SE                                         UN GHS • Specific Target Organ Toxicity Single Exposure 2
Toxicity for Reproduction                       UN GHS • Toxic to Reproduction 1
Germ Cell Mutagenicity                           UN GHS • Classification criteria not met

Target Organs: Heart/Cardiovascular System

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 include hypotension. Toxic if ingested in excess of prescription dose.
- **Chronic (Delayed)**: No data available

<table>
<thead>
<tr>
<th>Carcinogenic Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAS</strong></td>
</tr>
<tr>
<td>Ferric oxide red</td>
</tr>
</tbody>
</table>

Reproductive Effects: Pregnancy Category D. Use of drugs that act on the renin-angiotensin system during the 2nd and 3rd trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death.
Section 12 - Ecological Information

Toxicity

- Enalapril maleate - Daphnia magna (LC50, 48 hr) 354 mg/L; Pimephales promelas (LC50, 96 hr) >1000 mg/L

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>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Applicable</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>
<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>
<td>Not Applicable</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>Not Applicable</td>
<td>Not Regulated</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>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>144-55-8</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Corn starch</td>
<td>9005-25-8</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ingredient</td>
<td>CAS Number</td>
<td>WHMIS Classification</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>------------</td>
<td>-----------------------</td>
<td>------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Enalapril maleate</td>
<td>76095-16-4</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**Canada**

**Labor**

**Canada - WHMIS - Classifications of Substances**

- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 Uncontrolled product according to WHMIS classification criteria
- Corn starch 9005-25-8 Uncontrolled product according to WHMIS classification criteria
- Sodium bicarbonate 144-55-8 Uncontrolled product according to WHMIS classification criteria
- Ferric oxide yellow 51274-00-1 Uncontrolled product according to WHMIS classification criteria
- Lactose 63-42-3 Uncontrolled product according to WHMIS classification criteria
- Enalapril maleate 76095-16-4 Not Listed

**Canada - WHMIS - Ingredient Disclosure List**

- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 1 %
- Corn starch 9005-25-8 Not Listed
- Sodium bicarbonate 144-55-8 Not Listed
- Ferric oxide yellow 51274-00-1 Not Listed
- Lactose 63-42-3 Not Listed
- Enalapril maleate 76095-16-4 Not Listed

**United States**

**Environment**

**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 Not Listed
- Corn starch 9005-25-8 Not Listed
- Sodium bicarbonate 144-55-8 Not Listed
- Ferric oxide yellow 51274-00-1 Not Listed
- Lactose 63-42-3 Not Listed
- Enalapril maleate 76095-16-4 Not Listed

**United States - California**

**Environment**

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

- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 Not Listed
- Corn starch 9005-25-8 Not Listed
- Sodium bicarbonate 144-55-8 Not Listed
- Ferric oxide yellow 51274-00-1 Not Listed
Lactose 63-42-3 Not Listed
Enalapril maleate 76095-16-4 Not Listed

**U.S. - California - Proposition 65 - Developmental Toxicity**
- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 Not Listed
- Corn starch 9005-25-8 Not Listed
- Sodium bicarbonate 144-55-8 Not Listed
- Ferric oxide yellow 51274-00-1 Not Listed
- Lactose 63-42-3 Not Listed
- Enalapril maleate 76095-16-4 Not Listed

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**
- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 Not Listed
- Corn starch 9005-25-8 Not Listed
- Sodium bicarbonate 144-55-8 Not Listed
- Ferric oxide yellow 51274-00-1 Not Listed
- Lactose 63-42-3 Not Listed
- Enalapril maleate 76095-16-4 Not Listed

**U.S. - California - Proposition 65 - Reproductive Toxicity - Male**
- Magnesium stearate 557-04-0 Not Listed
- Ferric oxide red 1309-37-1 Not Listed
- Corn starch 9005-25-8 Not Listed
- Sodium bicarbonate 144-55-8 Not Listed
- Ferric oxide yellow 51274-00-1 Not Listed
- Lactose 63-42-3 Not Listed
- Enalapril maleate 76095-16-4 Not Listed

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**Section 16 - Other Information**

**Revision Date** 22/September/2015
**Last Revision Date** 22/September/2015
**Preparation Date** 22/September/2015

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