



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

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

Composition		
Chemical Name	Identifiers	%
Corn starch	CAS:9005-25-8 EINECS:232-679-6	N/A
Enalapril maleate	CAS:76095-16-4 EINECS:278-375-7	2.2% TO 9.9%
Ferric oxide red	CAS:1309-37-1 EINECS:215-168-2	N/A
Ferric oxide yellow	CAS:51274-00-1 EINECS:257-098-5	N/A
Lactose	CAS:63-42-3	N/A
Magnesium stearate	CAS:557-04-0 EINECS:209-150-3	N/A
Sodium bicarbonate	CAS:144-55-8 EINECS:205-633-8	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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	
	<ul style="list-style-type: none"> The most likely manifestation of overdose would be hypotension.
Indication of any immediate medical attention and special treatment needed	
Notes to Physician	<ul style="list-style-type: none"> Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.
Antidotes	<ul style="list-style-type: none"> 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.

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

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

- Considerations** 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

Material Description			
Physical Form	Solid	Appearance/Description	2.5 mg - white, oval tablet; 5 mg - white, rounded triangle tablet; 10 mg - rust red, rounded triangle tablet; 20 mg - peach, rounded triangle tablet.
Color	2.5 mg - white; 5 mg - white; 10 mg - rust red; 20 mg - peach.	Odor	No odor.
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	143 to 144.5 C(289.4 to 292.1 F)
Decomposition Temperature	No data available	pH	2.4 to 2.8
Specific Gravity/Relative Density	Not relevant	Water Solubility	Slightly Soluble
Solvent Solubility	Alcohol; Dimethylformamide; Methyl alcohol	Viscosity	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

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

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

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

Carcinogenic Effects		
	CAS	IARC
Ferric oxide red	1309-37-1	Group 3-Not Classifiable

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

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

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

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ferric oxide yellow	51274-00-1	Yes	Yes	Yes
Sodium bicarbonate	144-55-8	Yes	Yes	Yes
Corn starch	9005-25-8	Yes	Yes	Yes
Ferric oxide red	1309-37-1	Yes	Yes	Yes

Lactose	63-42-3	Yes	Yes	Yes
Enalapril maleate	76095-16-4	Yes	Yes	No
Magnesium stearate	557-04-0	Yes	Yes	Yes

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

Section 16 - Other Information

Revision Date • 22/September/2015

Last Revision Date • 22/September/2015

Preparation Date • 22/September/2015

Disclaimer/Statement of Liability • To the best of our knowledge, the information contained herein is accurate. However, neither Valeant Pharmaceuticals International, Inc. nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Valeant Pharmaceuticals International, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.