

SAFETY DATA SHEETS

This SDS packet was issued with item:

078321555

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078058858 078058866 078058882 078321563 078365981 078914811 078914812 078933128

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078086889 078321571

Wockhardt Limited

Safety Data Sheet

Section 1: Identification

Product Name: Enalapril Maleate Tablets

Synonyms: None

CAS Number: 76095-16-4

Product Use: Pharmaceutical active used as Antihypertensive

Manufacturer/Supplier: Wockhardt Limited

Address: Wockhardt Limited, Mumbai 400 051, India

General Information: 973-257-4960

Emergency Telephone Number: 1-800-346-6854

Section 2: Hazard(s) Identification

Appearance: Pharmaceutical Tablet

Odor: Not available

Physical State: Solid

Usual Adult Dose: The usual oral adult dose of Enalapril Maleate is 10 to 40 mg per day, as a single dose or divided doses.

Adverse Effects: Adverse effects include cough, diarrhea, headache, loss of taste, nausea, unusual tiredness, dizziness or fainting, skin rash, fever, joint pain and rarely chest pain, difficult breathing and swelling. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization

Inhalation: May cause irritation. Remove to fresh air

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation, Flush out mouth with water.

Medical Conditions Aggravated by Exposure: Hypersensitivity to the material, angioedema, active alcoholism, severe auto-immune disease, cerebrovascular or coronary insufficiency, diabetes mellitus impaired liver or kidney function, and hyperkalemia.

Cross Sensitivity: Persons intolerant of one of the other ACE inhibitors may be intolerant of this material also.

Pregnancy Comments: The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with serious fetal and neonatal injury or death; therefore the use of Enalapril Maleate should be avoided by pregnant woman.

Pregnancy Category: D

Section 3: Composition/Information on Ingredients

| Component | CAS Number | Weight % |
|-------------------|----------------------------------|--------------|
| Enalapril Maleate | 76095-16-4 | 10.0 |
| Lactose Anhydrous | 63-42-3 | Trade secret |
| Corn Starch | 9005-25-8 | Trade secret |
| Hypromellose | 9004-65-3 | Trade secret |
| Talc | 14807-96-6 | Trade secret |
| Stearic acid | 57-11-4 | Trade secret |
| Iron Oxide Red | 1309-37-1 | Trade secret |
| Iron Oxide Brown | 1309-37-1, 51274-00-1, 1317-61-9 | Trade secret |

Section 4: First-Aid Measures

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Overdose treatment consists of volume expansion for correction of hypotension.

Section 5: Fire-Fighting Measures

Flash Point: Not found

Upper Flammable Limit : Not found

Auto-ignition Temperature: Not found

Lower Flammable Limit : Not found

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire & Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.

Fire Fighting Procedures: As with all fires, evacuate personnel to safe area. Fire fighters should use self-contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

Personal Precautions: Wear approved respirator and chemically compatible gloves and protective clothing.

Environmental Precautions: Prevent product from entering drains. Local authorities should be advised if a significant spill can not be contained.

Methods for Cleaning up: Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust Place spillage in appropriately labeled container for disposal. Wash spill site thoroughly.

Section 7: Handling and Storage

Handling: As a general rule, when handling Enalapril Maleate avoids all contact and inhalation of dust, mists, and for vapours associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP - NF. This material should be handled and stored as per the label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Ventilation: Recommended

Gloves: Rubber, face shield

Eye Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

Section 9: Physical and Chemical Properties

Appearance & Odor: White to off-white crystalline powder.

Physical State: Solid

Melting Point: Not available

Boiling Point: Not applicable

Water Solubility: Soluble in water

Specific Gravity: Not applicable

Vapor Pressure: Not applicable

Vapor Density: Not applicable

Evaporation Rate: Not applicable

Reactivity in water: Not found

% Volatile by Volume: Not Found

Section 10: Stability and Reactivity

Conditions to Avoid: Not found.

Incompatibilities: Not found

Decomposition Products: When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stable: Yes

Hazardous Polymerisation: No

Section 11: Toxicological Information

Oral Rat : LD₅₀ : 2973 mg/Kg

Oral Mouse : LD₅₀ : 3507 mg/Kg

Irritancy Data : Not found

Target Organ(s) : Not found

Listed as a Carcinogen?: NTP : No IARC : No

OSHA. : No Other : No

Section 12: Ecological Information

Ecotoxicity : Not available

Environment toxicity : Not available

Special remarks on the product of biodegradation : Not available

Section 13: Disposal Considerations

Disposal: Dispose off waste in accordance with all applicable Federal, State and local laws.

Section 14: Transport Information

Transport Information: This material is not regulated for transportation as a hazardous material/dangerous goods.

Section 15: Regulatory Information

| | | |
|--|--|--------|
| Lactose Anhydrous: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |
| Corn Starch: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |
| Hypromellose: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |
| Talc: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |
| Stearic acid: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |
| Iron Oxide Red: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |
| Iron Oxide Brown: | | |
| Inventory - United States TSCA - Sect. 8(b) | | Listed |

Section 16: Other Information

Prepared by: Wockhardt Limited, Mumbai 400 051, India

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.