

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078058882

**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 078321555 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

PRODUCT : ENALAPRIL MALEATE

1. Identification of the Substance / preparation and the Company

Wockhardt Limited,  
138, GIDC Estate,  
Ankleshwar - 393002  
District Bharuch, Gujarat, INDIA.  
Phone No.: 91 2646 251316, 251293      Fax No.: 91 2646 251087

2. Composition / Information on Ingredient

Common Name	: Enalapril Maleate	Formula	: C <sub>20</sub> H <sub>28</sub> N <sub>2</sub> O <sub>5</sub> . C <sub>4</sub> H <sub>4</sub> O <sub>4</sub>
Synonyms	: Not found	M.W.	: 494
Chemical Name	: L-Proline, 1-{N-[1(ethoxycarbonyl)-3-phenylpropyl]-L-alanyl}-(S)-(Z)-2-butenedioate (1:1)		
CAS Number	: 76095-16-4	RTECS Number	: TW3666000
Chemical Family	: Not found		
Therapeutic Category	: Antihypertensive		

Principle Components	Percent	Exposure Limits
Enalapril Maleate	Pure Material	Not found

3. Health Hazards Information:

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

(Sr. Executive - Safety)

(Sr. Manager - QA)

**MATERIAL SAFETY DATA SHEET**

**Engineering  
(Safety)**

**MSDS-E01/2**

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**PRODUCT : ENALAPRIL MALEATE**

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

**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.

**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.

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**PRODUCT : ENALAPRIL MALEATE**

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

**6 Spill Response**

**Spill** : Wear approved respirator and chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site thoroughly.

**7 Handling and Storage**

**Handling** : As a general rule, when handling Enalapril Maleate avoid all contact and inhalation of dust, mists, and/or 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.

**8 Exposure control / Personnel 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.

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**PRODUCT : ENALAPRIL MALEATE**

**9 Physical & Chemical Properties**

Appearance and Odour : White to off-white crystalline powder.  
Melting Point : 143°C to 145°C  
Boiling Point : Not found  
Solubility in water : Sparingly soluble  
Specific Gravity : Not found  
Vapour Pressure : Not found  
Vapour density : Not found  
Evaporation Rate : Not found  
Reactivity in water : Not found  
% Volatile by Volume : Not found

**10 Stability and Reactivity Data**

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

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**PRODUCT : ENALAPRIL MALEATE**

**11 Toxicological Information**

Oral Rat : LD<sub>50</sub> : 2973 mg/Kg  
Oral Mouse : LD<sub>50</sub> : 3507 mg/Kg  
Irritancy Data : Not found  
Target Organ(s) : Not found  
Listed as a Carcinogen? : NTP : No IARC : No OSHA : No.  
: Other : No

**12 Ecological Information**

Ecotoxicity : Not available Environment toxicity : Not available  
Special remarks on the product of biodegradation : Not available

**13 Disposal Consideration**

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

**14 Transport Information**

Identification : Not applicable Special provision for Transport : Not applicable

**15 Regulatory Information**

Not available

**16 Other Information**

Product Use : Bulk Drug Other Special Consideration : Not available

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