

SAFETY DATA SHEETS

This SDS packet was issued with item:

078365981

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 078321555 078321563 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

MATERIAL SAFETY DATA SHEET

Engineering
(Safety)

MSDS-E01/2

07/06/2004
MSDS-E01/1
07/06/2004
JUN 2007
1 of 5

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 ₂₀ H ₂₈ N ₂ O ₅ . C ₄ H ₄ O ₄ |
| 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

**07/06/2004
MSDS-E01/1
07/06/2004
JUN 2007
2 of 5**

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.

(Sr. Executive - Safety)

(Sr. Manager - QA)

MATERIAL SAFETY DATA SHEET

**Engineering
(Safety)**

MSDS-E01/2

**07/06/2004
MSDS-E01/1
07/06/2004
JUN 2007
3 of 5**

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.

(Sr. Executive - Safety)

(Sr. Manager - QA)

MATERIAL SAFETY DATA SHEET

**Engineering
(Safety)**

MSDS-E01/2

**07/06/2004
MSDS-E01/1
07/06/2004
JUN 2007
4 of 5**

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

(Sr. Executive - Safety)

(Sr. Manager - QA)

MATERIAL SAFETY DATA SHEET

Engineering
(Safety)

MSDS-E01/2

07/06/2004
MSDS-E01/1
07/06/2004
JUN 2007
5 of 5

PRODUCT : ENALAPRIL MALEATE

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

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

(Sr. Executive - Safety)

(Sr. Manager - QA)