

## **SAFETY DATA SHEETS**

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

078948078

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

078894077 078948076 078948079 078948080 078948081 078948082 078948083



# SAFETY DATA SHEET

OSHA's Hazard Communication Standard 2012

## 1. Identification of the substance/preparation and the company/undertaking

GHS product identifier	
Product name	ENALAPRIL MALEATE TABLETS USP
Other means of identification	Not available
Synonym(s)	Formulated Product Enalapril Maleate Tablets USP, 2.5mg Enalapril Maleate Tablets USP, 5mg Enalapril Maleate Tablets USP, 10mg Enalapril Maleate Tablets USP, 20mg
UN-Number	n/a
Recommended use	Medicinal Product
	This safety data sheet is 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 medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Recommended restrictions	No other uses are advised.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	Zhejiang Huahai Pharmaceutical Co Ltd
	Xunqiao, Linhai, Zhejiang 317024, China
Normal business hour Beijing time 8:00AM-5:00PM	Phone No.: 008657685016952
Email Address	luweiming@huahaipharm.com
Emergency telephone number	008657685016952

## 2. Hazards Identification

Classified hazards
Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP] Reproductive toxicity (Category 2), H361 Acute toxicity (Category 5), H303
Label elements
INDICATIONS AND USAGE For treatment: 1. Primary hypertension in all stages 2. Renovascular hypertension 3. Heart failure at all levels is also suitable for patients with symptomatic heart failure: improving survival rate: delaying the progress of heart failure; Reduce hospitalization caused by heart failure. 4. Prevention of symptomatic heart failure for asymptomatic patients with left ventricular insufficiency, it is applicable to: delay the progress of symptomatic heart failure: reduce hospitalization caused by heart failure. 5. Prevent coronary ischemia events in patients with left ventricular insufficiency. It is applicable to: reduce the incidence of myocardial infarction; reduce hospitalization caused by unstable angina pectoris.



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### WARNINGS AND PRECAUTIONS

Symptomatic hypotension: symptomatic hypotension rarely occurs in hypertensive patients without complications. Hypertensive patients taking enalapril maleate have insufficient blood volume due to diuretic treatment, dietary salt restriction, dialysis, diarrhea or vomiting. Hypotension is more likely to occur (see drug interactions and side effects). Symptomatic hypotension has been observed in heart failure patients with or without renal insufficiency. Patients with severe heart failure are most likely to occur. This can be reflected by the use of large doses of diuretics, hyponatremia or functional renal insufficiency. Such patients should start treatment under medical monitoring, and close follow-up observation should be carried out whenever the dose of enalapril maleate or / and diuretics is adjusted. The same treatment also applies to patients with ischemic heart disease or cerebral blood.

Precautions during pregnancy and lactation:

Pregnancy 1. It is not recommended to use this drug during pregnancy. If found pregnant, unless it is necessary to save the mother's life. Otherwise, stop using this product immediately. 2. Angiotensin converting enzyme inhibitors used during the middle and last three months of pregnancy can cause fetal and neonatal morbidity and mortality. The use of angiotensin-converting enzyme inhibitors during this period is related to various fetal and neonatal injuries, including hypotension, renal failure, hyperkalemia, and / or neonatal head hypoplasia. There has been maternal oligohydramnios (presumably a manifestation of decreased fetal renal function) and can lead to limb spasm, craniofacial malformation and lung dysplasia. If the patient uses this product. The potential harm to the fetus should be explained to the patient. 3. In the first three months of pregnancy, the uterus is exposed to this angiotensin converting enzyme inhibitor. It will not cause the above adverse reactions to embryos and fetuses. 4. For those rare cases who must use angiotensin converting enzyme inhibitors during pregnancy, a series of ultrasound examinations should be carried out to evaluate the situation in the amnion. If too little amniotic fluid is found, the use of this product should be stopped. Unless it is necessary to save the mother's life. Patients and doctors should be aware that when oligohydramnios occurs, the fetus has suffered irreversible damage. 5. Infants born to mothers who have used this product should be closely observed to find out whether there is hypotension, oliguria and hyperkalemia. Enalapril can pass through the placenta. Peritoneal dialysis can clear it from the fetal blood circulation, which is clinically beneficial. In theory, it can be removed by blood exchange. Lactating mothers have a small amount of enalapril and enalapril (the hydrolysate of enalapril) secreted in human milk. Nursing mothers should be cautious when using this product.

### Hazard(s) not otherwise classified (HNOC)

Available hazard identification for Active Pharmaceutical Ingredient (API) alone:



Pictogram:

Signal word:

Warning

Hazard statement(s)

H361

Suspected of damaging fertility or the unborn child.

H302

Harmful if swallowed.

Precautionary statement(s)

P201

Obtain special instructions before use.

P202

Do not handle until all safety precautions have been read and understood.

P280

Wear protective gloves/ protective clothing/ eye protection/ face protection.

P308 + P313

IF exposed or concerned: Get medical advice/ attention.

P405

Store locked up. P501 Dispose of contents/ container to an approved waste disposal plant.



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Supplemental Hazard none  
Statements  
Other hazards  
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 3. Composition/Information on ingredients

### Mixtures

Hazardous components Chemical name	Common name and synonyms	CAS number	%
Enalapril Maleate		76095-16-4	2
Corn Starch		9005-25-8	10
Lactose Monohydrate		10039-26-6	83
Pregelatinized Starch		47261-18-7	3
Sodium Bicarbonate		144-55-8	1
Sodium Stearyl Fumarate		557-04-0	1

## 4. First aid measures

<b>Eye contact</b>	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
<b>Skin contact</b>	Wash off immediately with plenty of water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
<b>Inhalation</b>	Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration.
<b>Ingestion:</b>	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Symptoms: None known. Hazards: May cause mild eye/skin irritation.
<b>Indication of immediate medical attention and special treatment needed</b>	Treatment: None known





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<b>General information</b>	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
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### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Suitable extinguishing media: Water, Carbon dioxide (CO <sub>2</sub> ), Dry chemical, foam
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Dust may form explosive mixture in air. Hazardous decomposition products formed under fire conditions.
<b>Special protective equipment and precautions for firefighters</b>	Wear self contained breathing apparatus for fire fighting if necessary.
<b>Fire-fighting equipment /instructions</b>	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures:</b>	Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).
<b>Methods and materials for containment and cleaning up</b>	Do not sweep. Preferred method for spill cleanup is by using a HEPA equipped vacuum. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.
<b>Environmental precautions</b>	Try to prevent the material from entering drains or water courses. Refer to Sections 11 and 12 for health and environmental hazard information.

### 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. For personal protection see section 8.
<b>Conditions for safe storage, including any incompatibilities</b>	Requirements for storage areas and containers: Keep container tightly closed in a dry and well-ventilated place.

### 8. Exposure controls/personal protection

<b>Exposure Controls</b>
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<b>Engineering measures</b>	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure.
<b>Eye Protection</b>	Safety glasses with side-shields conforming to EN166
<b>Skin and Body Protection</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact. Protective gloves complying with EN 374.
<b>Respiratory Protection</b>	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. When using, do not eat, drink or smoke.
<b>Control parameters</b>	
<b>Components</b>	<b>Exposure Limit Values</b>
Enalapril Maleate	No data available.
Sodium Bicarbonate	TWA—5mg/m <sup>3</sup>
Magnesium Starch	TWA—3mg/m <sup>3</sup>

## 9. Physical and chemical properties

Physical state	Solid.		
Form	Tablet.		
Color	Strengths(mg)	Color	
	2.5	White	
	5	White	
	10	Red	
	20	Yellow	
Odor	Not available.		
Odor threshold	Not available.		
pH	Not available.		
Melting point/range	Not available.		
Boling point/boiling range	Not available.		
Flash point	Not available.		
Evaporation rate	Not available.		
Flammability (solid, gas)	Not available.		
Flammability limits in air	Not available.		



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Flammability limit – upper (%)	Not available.
Flammability limit – lower (%)	Not available.
Explosive limit – lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific gravity	Not available.
Watersolubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient: (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Product Description	
Strengths	Product Description
2.5mg	White, oval shaped scored tablet, debossed with "S 1" and scored on one side, "S" and "1" are separated by the score and plain on the other side.
5mg	White, rounded triangle shaped scored tablet debossed with "S 6" on one side and scored on the other side.
10mg	Red, rounded triangle shaped scored tablet debossed with "S 7" on one side and scored on the other side.
20mg	Yellow, round scored tablet, debossed with "S 11" and scored on one side, "S 11" is on one side of the score and plain on the other side.

## 10. Stability and reactivity

Reactivity	Reaction with water: Not water reactive.
Chemical stability	Stable under proper conditions.
Possibility of hazardous reaction	No special reactivity has been reported.
Conditions to avoid	No data available.
Incompatible material	Oxidizing agents.
Hazardous decomposition products	Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx), Hydrogen fluoride, Hydrogen chloride
Other decomposition products - no data available	

## 11. Toxicological information

Information on Toxicological Effects
Acute toxicity



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Components	Species	Test Results
Enalapril Maleate(CAS 76095-16-4) orl-rat LD50:2973 mg/kg scu-rat LD50:1418 mg/kg ivn-rat LD50:849 mg/kg		
Skincorrosion/irritation	No data available.	
Serious eye damage/eye irritation	No data available.	
Respiratory sensitization	No data available.	
Germ Cell Mutagenicity	No data available.	
Carcinogenicity	No data available.	
Reproductive Toxicity	orl-wmn TDLo:6800 ug/kg (32-34W preg) orl-rat TDLo:280 mg/kg (15-22D preg/20D post)	
Specific Target Organ Toxicity (Single Exposure)	No data available.	
Specific Target Organ Toxicity (Repeated Exposure)	No data available.	
Aspiration Hazard	No data available.	
Additional Information	RTECS: Not available	

## 12. Ecological information

Toxicity	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	No data available
Other adverse effects	No data available

## 13. Disposal considerations

Disposal instructions	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
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Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	No data available
Waste from residues / unused products	Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging	Dispose of as unused product.

## 14. Transport information

Special precautions for users	Not dangerous goods in the meaning of ADR, IMO/IMDG, ICAO/IATA.
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## 15. Regulatory information

This safety data sheet complies with the requirement of Regulation (EC) No.1907/2006
Regulations on the Control over Safety of Dangerous Chemicals (State Council announces on January 26, 2002 and revised on February 16, 2011): Safe use and production, the storage of a dangerous chemical, transport, loading and unloading were prescribed.

## 16. Other information

Issue date	30.07.2022
Revision date	30.07.2022
Version #	058A
Reference	1) SIGMA-ALDRICH ENALAPRIL MALEATE SDS 2) TCI ENALAPRIL MALEATE SDS

### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet

Signature: 卡伟明