

# Enalapril maleate

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 25/03/2015 Revision date: 15/02/2017

**1693867**

Version: 2.0

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product form : Substance  
Substance name : Enalapril maleate  
Chemical name : N-(N-(1S)-1-Ethoxy Carbonyl-3-phenylpropyl)-L-alanyl)-L-proline Hydrogen maleate  
EC-No. : 278-375-7  
CAS-No. : 76095-16-4  
Product code : 1693867  
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>  
Product group : Raw material

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical  
Industrial/Professional use spec : Industrial  
For professional use only  
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals  
Function or use category : Raw material

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

Duchefa Farma BV  
A. Hofmanweg 71  
2031BH Haarlem - The Netherlands  
T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
+31(0)23-5319093 (M-F 09:00-17:00)  
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Serious eye damage/eye irritation, Category 1	H318
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Reproductive toxicity, Category 2	H361d

Full text of hazard classes and H-statements : see section 16

**Adverse physicochemical, human health and environmental effects**

No additional information available

**2.2. Label elements****Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H318 - Causes serious eye damage  
H361d - Suspected of damaging the unborn child  
H362 - May cause harm to breast-fed children

Precautionary statements (CLP)

: P263 - Avoid contact during pregnancy/while nursing  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 - IF IN EYES:  
P351 - Rinse cautiously with water for several minutes  
P308+P313 - IF exposed or concerned: Get medical advice/attention

**2.3. Other hazards**

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

**SECTION 3: Composition/information on ingredients****3.1. Substances**

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Enalapril maleate	(CAS-No.) 76095-16-4 (EC-No.) 278-375-7	≈ 100	Eye Dam. 1, H318 Lact., H362 Repr. 2, H361d

Full text of H-statements: see section 16

**3.2. Mixtures**

Not applicable

**SECTION 4: First aid measures****4.1. Description of first aid measures**

First-aid measures general	: Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention. Call a POISON CENTER or doctor/physician. Apply artificial respiration if breathing stopped.
First-aid measures after inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

**4.2. Most important symptoms and effects, both acute and delayed**

Symptoms/effects	: May damage fertility, May damage the unborn child. Causes damage to organs (Damage to kidneys and liver). Causes damage to organs (Cardiac and blood circulation effects) through prolonged or repeated exposure.
Symptoms/effects after eye contact	: Causes serious eye damage.
Symptoms/effects after ingestion	: Swallowing a small quantity of this material will result in serious health hazard.

**4.3. Indication of any immediate medical attention and special treatment needed**

No additional information available

**SECTION 5: Fire-fighting measures****5.1. Extinguishing media**

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

**5.2. Special hazards arising from the substance or mixture**

Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO <sub>2</sub> ). Nitrogen oxides.
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**5.3. Advice for firefighters**

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

Emergency procedures	: Evacuate unnecessary personnel.
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**6.1.2. For emergency responders**

Protective equipment	: Equip cleanup crew with proper protection.
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Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Store away from other materials.

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Provide appropriate exhaust ventilation at places where dust is formed. Avoid raising dust.

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. Do not breathe dust, gas, vapours, mist.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed parts thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Provide local exhaust or general room ventilation.

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Water, humidity. Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Carry out operations in the open/under local exhaust/ventilation or with respiratory protection. Facilities: shower, eye shower.

#### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

#### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

**Skin and body protection:**

Protective clothing (with elasticated cuffs and closed neck). Chemical resistant apron. Long sleeved protective clothing

**Respiratory protection:**

Dustmask with filtertype P3

**Other information:**

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 492.52 g/mol
Colour	: White.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: 2.4 - 2.9 (1% oplossing)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 144 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: 432 °C
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: < 0.0000001 kPa
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Moderately soluble in water. Soluble in ethanol.
Log Pow	: -2
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

**10.2. Chemical stability**

Stable under normal conditions.

**10.3. Possibility of hazardous reactions**

Not established.

**10.4. Conditions to avoid**

Direct sunlight. Extremely high or low temperatures.

**10.5. Incompatible materials**

Strong acids. Strong bases.

**10.6. Hazardous decomposition products**

Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. fume. Carbon monoxide. Carbon dioxide.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

Acute toxicity : Not classified

<b>Enalapril maleate (76095-16-4)</b>	
LD50 oral rat	> 2000 mg/kg
LD50 oral	3696 mg/kg mouse (male); 3507 (female)

Skin corrosion/irritation	: Not classified pH: 2.4 - 2.9 (1% oplossing)
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Causes serious eye damage. pH: 2.4 - 2.9 (1% oplossing)
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: May cause harm to breast-fed children. Suspected of damaging the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Harmful if swallowed.

**SECTION 12: Ecological information****12.1. Toxicity**

<b>Enalapril maleate (76095-16-4)</b>	
LC50 fish 1	> 1000 mg/l
EC50 Daphnia 1	364 mg/l

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### 12.2. Persistence and degradability

Enalapril maleate (76095-16-4)	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Enalapril maleate (76095-16-4)	
Log Pow	-2
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

### 14.6. Special precautions for user

#### - Overland transport

No data available

#### - Air transport

No data available

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Enalapril maleate is not on the REACH Candidate List

Enalapril maleate is not on the REACH Annex XIV List

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier. EP. EDQM.

Other information : None.

Full text of H- and EUH-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 2	Reproductive toxicity, Category 2
H318	Causes serious eye damage
H361d	Suspected of damaging the unborn child
H362	May cause harm to breast-fed children

SDS EU (REACH Annex II) Version 2017

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*



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