

SAFETY DATA SHEET

Section 1: Identification	
Material	Enalapril Maleate Oral Solution 1 mg/ mL
Other means of identification	Enalapril Maleate Oral Solution
Recommended use	Pharmaceutical product
Recommended restrictions	NA
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard Classification:	Not Classified as Hazardous under GHS.
Label Elements (Hazcom 2012)	This product is not classified as hazardous in accordance with the GHS criteria (29 CFR 1910.1200). No labelling required.
P264	Wash hands thoroughly after handling product
P302+P352	If ON SKIN: wash with plenty of water.
P332+P313	If skin irritation or rash occurs: Get medical attention or advice.
P305+P351+P338	If IN EYES: Rinse continuously with water for several minutes. Remove contacts if present and easy to do. Get medical attention or advice.
P304+P341	If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a comfortable position for breathing
P273	Avoid release to the environment.
Section 3: Composition/Information on Ingredients	
Active Ingredient	
Enalapril Maleate	
CAS	76095-16-4
Section 4: First-Aid Measures	
Product is not likely to present problems during normal handling, but in case of excessive exposure the following measures may be required;	
Ingestion	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.
Eye Contact	Flush eyes with water for 15 minutes. Get medical attention.
Inhalation	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Measures-General Advice	Consult a physician or poison control center. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

<p>Most important symptoms/effects, acute and delayed</p>	<p>Causes serious eye irritation Causes skin irritation Irritating to respiratory system May cause abdominal pain, nausea, vomiting, diarrhea May cause constipation May cause dyspepsia Weakness May cause muscle pain Dryness of mouth Dyspnea (Shortness of breath and difficulty breathing) May affect respiration Hyperkalemia Central nervous system effects May cause drowsiness or dizziness Fatigue Convulsions Ataxia vertigo Hallucinations Headache May affect the cardiovascular system Chest tightness or pain Hypotension Weak, rapid pulse or rapid heart rate (Tachycardia) Bradycardia Heart palpitations May affect the blood May affect the liver It may affect the kidneys May affect the bone marrow Paresthesia (numbness and tingling of the extremities)</p>
<p>Indication of any immediate medical attention and special treatment needed</p>	<p>Treat symptomatically.</p>
<p>Protection of first-aiders</p>	<p>First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.</p>
<p>Section 5: Fire-Fighting Measures</p>	
<p>Suitable extinguishing media</p>	<p>Carbon dioxide (CO₂). Dry chemical. Water spray mist or foam.</p>
<p>Specific hazards arising from the chemical</p>	<p>Carbon Oxides. Nitrogen Oxides</p>
<p>Advice for firefighters</p>	<p>As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.</p>
<p>Further information</p>	<p>No data available</p>
<p>Section 6: Accidental Release Measures</p>	
<p>Personal precautions, protective equipment and emergency procedures</p>	<p>Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Avoid breathing dust. Remove all sources of ignition.</p>
<p>Environmental precautions</p>	<p>Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers,</p>

Section 10: Stability and Reactivity	
Reactivity	May react with strong oxidizers
Chemical stability	Stable under normal use and storage conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur
Conditions to avoid	Heat.
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	Carbon oxides. Nitrogen oxides (NOx)
Section 11: Toxicological Information	
Information on toxicological effects (based on Enalapril Maleate)	
Acute toxicity	
LD50 Oral-rat	2973 mg/kg Oral LD50 Rat
LD50 Oral-mouse	No information available
LD50 Dermal-rabbit	No information available
LD50 Dermal-rat	No information available
Skin Contact:	Causes skin irritation.
Eye Contact:	Causes serious eye irritation
Inhalation	Irritating to respiratory system.
Ingestion	May be harmful if swallowed. May cause flushing and sweating. May cause anorexia. May cause abdominal pain. Ingestion may cause nausea, vomiting. May cause diarrhea. May cause constipation. May cause dyspepsia. May cause muscle cramps. May cause weakness. May affect respiration (dyspnea, respiratory depression). May cause cyanosis. May cause coughing. May cause dry mouth. May cause stomatitis. May cause loss of taste. May cause hyperkalemia. May cause chest pain. May affect the cardiovascular system (slow heart rate (bradycardia)). May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (hypotension). May affect the cardiovascular system (palpitations). It may affect the kidneys and liver. May affect the blood. It may affect the blood (blood clotting factors). May cause dermatitis. May cause allergic reaction characterized by a rash. May cause blurred or foggy vision. May cause fainting. May affect behavior/central nervous system (convulsions/seizures). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (somnia). May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (lethargy, fatigue). May affect behavior/central nervous system (dizziness, headache).
Section 12: Ecological Information	
Ecotoxicity effects:	No data available.
Persistence and degradability	No data is available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.

Section 13: Disposal Considerations	
Waste treatment methods	Waste must be disposed of in accordance with Federal, State and Local regulation.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal
Section 14: Transport Information	
DOT (US) UN-No:	Not Regulated
IMDG UN-No:	Not Regulated
IATA UN-No:	Not Regulated
Product is a FDA regulated product: follow proper FDA regulations for packaging and transport of product.	
Section 15: Regulatory Information	
California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.	
Section 16: Other Information, including date of preparation or last revision	
<p>Issue Date: 01-02-2022</p> <p>Version: 00</p> <p>Further information</p> <p>Revision date: New Issue</p> <p>Revision note: New Issue</p> <p>The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.</p> <p>Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.</p>	