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: Com	position/Information on Ingredients	
Active Ingredient		
Enalapril Maleate CAS	76095-16-4	
CAS	76095-16-4	
	tion 4: First-Aid Measures	
	blems during normal handling, but in case of excessive exposure	
the following measures may be req	Do not induce vomiting without medical advice. Never give	
Ingestion	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.	

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Most important	Causes serious eye irritation	
symptoms/effects,	Causes skin irritation	
acute and delayed	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)	
Indication of any immediate	Treat symptomatically.	
medical attention and special	riou symptomationly.	
treatment needed		
Protection of first-aiders	First-Aid Providers: Avoid exposure to blood or body fluids. Wear	
Protection of hist-alders		
	gloves and other necessary protective clothing. Dispose of	
	contaminated clothing and equipment as bio-hazardous waste.	
Section	on 5: Fire-Fighting Measures	
Suitable extinguishing media	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.	
Specific hazards arising from the	Carbon Oxides. Nitrogen Oxides	
chemical	ř l	
Advice for firefighters	As in any fire, wear self-contained breathing apparatus pressure-	
	demand, MSHA/NIOSH (approved or equivalent) and full	
	protective gear.	
Further information	No data available	
Section	Section 6: Accidental Release Measures	
Personal precautions, protective	Ensure adequate ventilation. Keep people away from and upwind	
equipment and emergency	of spill/leak. Do not touch damaged containers or spilled material	
procedures	unless wearing appropriate protective clothing. Avoid contact with	
F	skin, eyes and clothing. Use personal protective equipment.	
	Avoid breathing dust. Remove all sources of ignition.	
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let	
	product enter drains. Prevent entry into waterways, sewers,	
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	basements or confined areas.		
Methods and materials for	Stop leak if you can do it without risk. Cover with plastic sheet to		
containment and cleaning up	prevent spreading. Sweep up and shovel into suitable containers		
	for disposal. Clean contaminated surface thoroughly		
Secti	on 7: Handling and Storage		
Precautions for safe handling	Wear personal protective equipment. Avoid contact with skin,		
	eyes and clothing. Do not ingest. Do not breathe dust. Use only		
	in well-ventilated areas. Keep away from heat and sources of		
	ignition. Handle in accordance with good industrial hygiene and		
Conditions for onto store as	safety practice.		
Conditions for safe storage,	Keep container tightly closed in a dry and well-ventilated place.		
including any incompatibilities	Store at room temperature in the original container. Store away		
Incompatible Materials:	from incompatible materials. Strong oxidizing agents		
incompatible waterials.	Strong oxidizing agents		
	Section 8: Exposure Controls/Personal Protection		
Exposure controls			
Engineering measures to reduce	Provide exhaust ventilation or other engineering controls to keep		
exposure:	the airborne concentrations of vapors and mist below their respective threshold limit value.		
Personal protective equipment			
Personal protective equipment			
Eye/face protection	Safety glasses with side-shields or Goggles		
Skin & Body Protection	Long sleeved clothing		
-	Gloves		
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately		
	after handling the product.		
	Effective dust mask. Use a dust respirator under conditions		
Respiratory protection	where exposure to the substance is apparent (e.g. generation of		
	high concentration of dust (dust clouds), inadequate ventilation,		
	development of respiratory tract irritation), and engineering		
	controls are not feasible. Be sure to use an approved/certified		
	respirator or equivalent		
Section 9:	Physical and Chemical Properties		
Information on basic physical and	chemical properties		
Appearance	Oral Solution		
Physical State	Solution		
Description	Enalapril maleate oral solution is a ready-to-use oral solution that		
	contains 1 mg/mL of enalapril maleate. It is clear, colorless		
	solution with a strawberry flavor, packaged in a 150 mL white,		
	round high-density polyethylene bottle with a white,		
	polypropylene, child resistant closure with induction seal FSE.		
	Each bottle contains 150 mL.		
	Bottle of 150 mL NDC- 31722-020-15		
	Store refrigerated (2° to 8°C/36° to 46°F) in a tightly closed		
	container. Protect from freezing and excessive heat. Patients		
	may store enalapril maleate oral solution at room temperature (20° to 25°C/68° to 77°F) for up to 60 days.		
	(20, 10, 25, 0, 00, 10, 17, 10) up to build ups.		

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 effect	s (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 (confusion). May affect	
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 RegulatedIMDG UN-No:Not RegulatedIATA 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

Issue Date: 01-02-2022

Version: 00

Further information

Revision date: New Issue

Revision note: New Issue

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.

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.