



SAFETY DATA SHEET

Section 1: Identification	
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GHS Product identifier	Captopril Tablets USP 12.5 mg, 25 mg, 50 mg and 100 mg.
Trade Name	Captopril Tablets
Other means of identification Synonyms	Captopril Tablets, Finished Product N-[(S)-3-Mercapto-2-methylpropionyl]-L-proline
Recommended use	Pharmaceutical product for the treatment of hypertension, nephropathy in type 2 Diabetic patients, heart failure and Left Ventricular Dysfunction after Myocardial Infarction.
Manufacturer	CorePharma, LLC, Middlesex, NJ 08846
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ, 08854.
Section 2: Hazard(s) Identification	
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Physical hazards	
Health hazards	No data available
OSHA defined hazards	No data available
Skin Sensitization	Category 1
Reproductive toxicity	Category 2
Specific target organ toxicity	No data available
Label elements	
Hazard symbol	
Signal word	Warning
Hazard statement	H361: May cause an allergic skin reaction. H317: Suspected of damaging fertility or the unborn child
Precautionary statement	
Prevention	P280- Wear protective gloves.
Response	If exposed or concerned: Get medical attention
Storage	Store locked up
Disposal	Dispose of in accordance with applicable regional, national and local laws and regulations.

Hazard(s) not otherwise classified (HNOC)		Not classified.
Section 3: Composition/Information on Ingredients		
Chemical Name	Common Name and Synonym	CAS
N-[(S)-3-Mercapto-2-methylpropionyl]-L-proline	N-[(S)-3-Mercapto-2-methylpropionyl]-L-proline	62571-86-2
Composition comments	Captopril tablets consist of Captopril as active pharmaceutical ingredient and Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Silicon Dioxide and Magnesium Stearate as excipients.	
	Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.	
Section 4: First-Aid Measures		
Inhalation	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.	
Skin Contact	In case of contact, Wash off with soap and plenty of water. Consult a physician.	
Eye Contact	In case of eye contact , Flush eyes with water as a precaution.	
Ingestion	If swallowed, never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.	
Most important symptoms/effects, acute and delayed	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.	
Indication of immediate medical attention and special treatment needed	No data available	
General information	No data available	
Section 5: Fire-Fighting Measures		
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Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.	
Unsuitable Extinguishing Media	No data available	
Specific hazards arising from the chemical	Carbon oxides, nitrogen oxides (NOx), Sulphur oxides	
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus for firefighting if necessary.	
Section 6: Accidental Release Measures		
Section 6, Accidental release measures		
Personal precautions, protective equipment and Emergency procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.	

Methods and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.	
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.	
Section 7: Handling and Storage		
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Precautions for safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.	
Conditions for safe storage, including any incompatibilities	Store in cool place. Keep container tightly closed in a dry and well-ventilated place.	
Section 8: Exposure Controls/Personal Protection		
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Occupational exposure limits		
Hetero (LEG) Components	Type	Value
Captopril (CAS 62571-86-2)	N/A	N/A
Biological limit values	No biological exposure limits noted for the ingredient(s)	
Appropriate engineering controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.	
Individual protection measures, such as personal protective equipment		
Eye/ Face protection	Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).	
Skin protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (Without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.	
Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).	
Thermal hazards	Not available	
General hygiene considerations	Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.	

Section 9: Physical and Chemical Properties

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Appearance	
Physical State	Solid
Form	Tablets
Color	White to off-white
Odor	Not applicable
Description	<p>12.5 mg tablets: White to Off white, round, uncoated tablets, debossed with “C” above the bisect and “32” below the bisect on one side and plain on other side.</p> <p>25 mg tablets: White to Off white, round, uncoated tablets, debossed with Quadrasect inside and “C33” on other side.</p> <p>50 mg tablets: White to Off white, capsule shaped, uncoated tablets, debossed with “C” before the bisect and “34” after the bisect on one side and plain on other side.</p> <p>100 mg tablets: White to Off white, capsule shaped, uncoated tablets, debossed with “C” before bisect and “35” after the bisect on one side and plain on other side.</p>

Section 10: Stability and Reactivity

Section 10, Stability and reactivity	
Reactivity	No data available
Chemical stability	No data available
Possibility of hazardous reactions	No data available
Conditions to avoid	No data available
Incompatible materials	No data available
Hazardous decomposition products	No data available

Section 11: Toxicological Information

Information on toxicological effects		
Acute toxicity		
Components	Species	Test Results
Captopril (CAS 62571-86-2)		
Acute		
Oral – LD50	Rat	4.245 mg/kg
Skin corrosion/irritation	No data available	
Serious eye damage/eye irritation	No data available	

sensitization	May cause allergic skin reaction.
Specific target organ toxicity – single exposure (STOT-SE)	No data available
Specific target organ toxicity – repeated exposure (STOT-RE):	No data available
Effects of short-term (acute) exposure	No data available
Effects of long-term (chronic) exposure	No data available
Carcinogenicity	IARC - No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
IARC Monographs. Overall Evaluation of Carcinogenicity	No data available
OSHA Specifically Regulated Substances	No data available
US. National Toxicology Program (NTP) Report on Carcinogens	No data available
Reproductive toxicity and teratogenicity	Possible risk of congenital malformation in the fetus. Suspected human reproductive toxicant
Aspiration hazard	No data available
Mutagenicity	No data available

Section 12: Ecological Information

Ectotoxicity: Harmful to aquatic life with long lasting effects.

Components		Species	Test Results
Captopril (CAS 62571-86-2)			
Toxicity on Invertebrates			
Acute			
EC50		N/A	N/A
Chronic			
NOEC		N/A	N/A
Fish	LC50	N/A	N/A
Chronic	NOEC	N/A	N/A
Other	EbC50	N/A	N/A
	ErC50		N/A
	EC50	N/A	N/A
Persistence and degradability		No data available	
Bioaccumulative potential		No data available	
Mobility in soil		No data available	

Section 13: Disposal Considerations

Disposal of product waste	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Disposal of packaging waste	Dispose of as unused product.

Section 14: Transport Information	
U.S. DOT	
No data available	
ICAO/IATA	
Not dangerous goods	
IMDG	
Not dangerous goods	
Section 15: Regulatory Information	
US regulations	No data available
CERCLA Hazardous Substance List (40 CFR 302.4)	No data available
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)	No data available
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)	No data available
SARA Title III	
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)	No data available
Section 313 Toxic Release Inventory (40 CFR 372)	No data available
Section 16: Other Information, including date of preparation or last revision	
Further information	
<p>The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide.</p> <p>The information this document is based on the resent state of our knowledge and is applicable to the product with regard to appropriate safety precautions.</p> <p>It does not represent any guarantee of the properties of the product. guidechem shall not be held liable for any damage resulting from handling or from contact with the above product.</p>	