# **SAFETY DATA SHEET**



### 1. Identification

Product identifier Captopril Disulfide

Other means of identification

 Catalog number
 1091221

 CAS number
 64806-05-9

Chemical name L-Proline, 1,1'-[dithiobis(2-methyl-1-oxo-3,1-propanediyl)]bis-[S-(R\*, R\*)]-

**Recommended use** Specified quality tests and assay use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

**Telephone** RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

## 2. Hazard(s) identification

Physical hazards Not classified.

Health hazardsSensitization, skinCategory 1

Reproductive toxicity Category 1

Specific target organ toxicity, repeated

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement May cause an allergic skin reaction. May damage fertility or the unborn child. May cause damage

to organs (cardiovascular system) through prolonged or repeated exposure.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective

gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be

Category 2 (cardiovascular system)

allowed out of the workplace.

**Response** If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.

Get medical advice/attention if you feel unwell.

Storage Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Material name: Captopril Disulfide USP SDS US

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmaceutical related compound of unknown potency.

## 3. Composition/information on ingredients

**Substance** 

Chemical name	Common name and synonyms	CAS number	%
Captopril Disulfide		64806-05-9	100

### 4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

Remove contaminated clothing immediately and wash skin with soap and water. Get medical Skin contact

attention if irritation develops and persists. For minor skin contact, avoid spreading material on unaffected skin. In case of eczema or other skin disorders: Seek medical attention and take along

these instructions.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion Cardiovascular effects. Pharmaceutical related compound of unknown potency. It is not known if Most important

occupational exposure may cause physiological effects. symptoms/effects, acute and

delayed

Provide general supportive measures and treat symptomatically. Treatment of ACE inhibitor Indication of immediate overdose should include the following: Administer activated charcoal as a slurry. For hypotension. medical attention and special infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. To reverse treatment needed hypotension in patients not responding to volume or pressor infusions, treat with angiotensin infusion. Naloxone has also been successful in reversing hypotension. For angioedema, administer antihistamines and corticosteroids. Monitor airway carefully and administer oxygen.

May be removable by hemodialysis.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from **General information** 

an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must

receive immediate medical attention.

### 5. Fire-fighting measures

Suitable extinguishing media Water, Foam, Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment

and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

Material name: Captopril Disulfide USP SDS US 2/6

## 7. Handling and storage

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of Precautions for safe handling

dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a

risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per

label instructions to ensure product integrity.

### 8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).

**Biological limit values** No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

**Hand protection** Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

> disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

### 9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot. **Appearance** 

Solid. **Physical state** 

**Form** Solid. Crystalline powder.

White. Color Odor Sulphurous. **Odor threshold** Not available. Not available. Ha

Melting point/freezing point 435.2 - 438.8 °F (224 - 226 °C)

452.3 - 453.2 °F (233.5 - 234 °C)

Initial boiling point and boiling

range

Not available.

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

Explosive limit - lower (%) Not available.

USP SDS US

Explosive limit - upper (%)Not available.Vapor pressureNot available.Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

**Solubility (other)**Methanol: Slightly soluble.
Ethanol: Slightly soluble.

DMSO: Slightly soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Molecular formula C18H28N2O6S2

Molecular weight 432.56

## 10. Stability and reactivity

**Reactivity**The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Stable at normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

**Hazardous decomposition** 

products

NOx. SOx. H2S. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

### 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Knowledge about health hazard is incomplete.

**Skin contact** May cause an allergic skin reaction.

**Eye contact** Knowledge about health hazard is incomplete.

**Ingestion** Based on a related compound, this material may cause: Cardiovascular effects.

Symptoms related to the physical, chemical and toxicological characteristics

ACE inhibitors: Dizziness. Rash. Joint pain. Cough. Chest pain. Confusion. Irregular heartbeat. Difficulty breathing. Numbness or tingling in hands, feet, or lips. Tiredness. Weakness. Muscle

cramps.

### Information on toxicological effects

Acute toxicity Not known.

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

**Respiratory sensitization** Knowledge about health hazard is incomplete.

**Skin sensitization** May cause an allergic skin reaction.

Germ cell mutagenicity

Knowledge about health hazard is incomplete.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

A related material has not caused cancer in animal studies.

### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### **US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

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May damage fertility or the unborn child. Reproductive toxicity

> The therapeutic use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with serious fetal and newborn injury, including growth retardation, renal impairment, oligohydramnios, hypocalvaria, fetal pulmonary hypoplasia, reduced fetal blood pressure, newborn anuria, patent ductus steriosus, and death. Prematurity can also occur. ACE inhibitors have demonstrated little or no teratogenicity in animal studies. No evidence of birth defects were seen in animal studies with a related material.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

May cause damage to organs (cardiovascular system) through prolonged or repeated exposure.

repeated exposure

Based on available data, the classification criteria are not met.

**Aspiration hazard Further information** 

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

## 12. Ecological information

**Ecotoxicity** 

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this substance.

**Bioaccumulative potential** Mobility in soil

No data available. No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** 

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

#### DOT

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

**General information** 

the IBC Code

Not applicable.

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US** federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)** 

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Material name: Captopril Disulfide USP SDS US

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

Classified hazard

Respiratory or skin sensitization

Reproductive toxicity

categories

Specific target organ toxicity (single or repeated exposure)

#### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

#### **US** state regulations

### **California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

### 16. Other information, including date of preparation or last revision

Issue date 03-09-2006 06-01-2020 Revision date

Version #

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