



# SAFETY DATA SHEET

## 1. Identification

Product identifier	Trandolapril	
Other means of identification		
Catalog number	1672687	
CAS number	87679-37-6	
Chemical name	(2S,3aR,7aS)-1-[(S)-N-[(S)-1-Carboxy-3-phenylpropyl]alanyl]hexahydro-2-indolinecarboxylic acid, 1-ethyl ester	
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 & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1A
	Specific target organ toxicity, repeated exposure	Category 2 (cardiovascular system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	May damage fertility or the unborn child. May cause damage to organs (cardiovascular system) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	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.
<b>Response</b>	If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Trandolapril		87679-37-6	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Hypotension. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Treatment of ACE inhibitor overdose should include the following: Administer activated charcoal as a slurry. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. To reverse 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.
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from 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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials. Cool containers exposed to flames with water until well after the fire is out.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	For waste disposal, see section 13 of the SDS. 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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of 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.
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**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**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Exposure limit values**

**Industrial Use  
Material**

**Type**

**Value**

Trandolapril (CAS  
87679-37-6)

TWA

2 micrograms/m3

**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**

**Eye/face protection**

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

Handle in accordance with good industrial hygiene and safety practice. 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**

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

**Physical state**

Solid.

**Form**

Powder.

**Color**

White.

**Odor**

Odorless.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

257 °F (125 °C)

**Initial boiling point and boiling  
range**

Not available.

**Flash point**

Not available.

**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.

<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Slightly soluble.
<b>Solubility (other)</b>	Anhydrous ethanol: Sparingly soluble. Chloroform: Soluble. Methanol: Soluble. Methylene chloride: Soluble.
<b>Partition coefficient (n-octanol/water)</b>	2.444
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Indole.
<b>Molecular formula</b>	C <sub>24</sub> H <sub>34</sub> N <sub>2</sub> O <sub>5</sub>
<b>Molecular weight</b>	430.54 g/mol

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Oxidizers.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NO <sub>x</sub> .

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Based on information from therapeutic use, this material may cause: Cardiovascular effects.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	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

Product	Species	Test Results
Trandolapril (CAS 87679-37-6)		
<b>Oral</b> LD50	Dog	2000 mg/kg
	Mouse	3990 mg/kg
	Rat	> 5000 mg/kg
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.	
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.	

**Respiratory or skin sensitization**

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

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

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

**Mutagenicity**

Ames assay

Result: Negative

In vivo mouse micronucleus test

Result: Negative

Point mutation and chromosome aberration assay in Chinese

hamster V79 cells

Result: Negative

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

25 mg/kg/day Long-term carcinogenicity study

Result: Negative

Species: Mouse

Test Duration: 18 months

8 mg/kg/day Long-term carcinogenicity study

Result: Negative

Species: Rat

Test Duration: 2 years

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

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

Not listed.

**Reproductive toxicity**

May damage fertility or the unborn child.

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 arteriosus, and death. Prematurity can also occur. ACE inhibitors have demonstrated little or no teratogenicity in animal studies. Knowledge about health hazard is incomplete.

**Reproductivity**

0.8 mg/kg/day Reproductivity study

Result: No increase in birth defects

Species: Rabbit

100 mg/kg/day Reproductivity study

Result: No impairment of fertility

Species: Rat

1000 mg/kg/day Reproductivity study

Result: No increase in birth defects

Species: Rat

25 mg/kg/day Reproductivity study

Result: No increase in birth defects

Species: Monkey

300 mg/kg/day Fertility study

Result: No effects on fertility and neonatal development and viability

Species: Rat

> 0.4 mg/kg/day Reproductivity study, administered orally

Result: Maternal toxicity

Species: Rabbit

**Specific target organ toxicity - single exposure** Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure** May cause damage to organs (cardiovascular system) through prolonged or repeated exposure.

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

**Further information** Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

## 12. Ecological information

<b>Ecotoxicity</b>	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.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	
<b>Octanol/water partition coefficient log Kow</b>	
2.444	
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	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

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>DOT</b>	
Not regulated as dangerous goods.	
<b>IATA</b>	
Not regulated as dangerous goods.	
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.
<b>General information</b>	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

<b>US federal regulations</b>	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	
Not regulated.	
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	
Not listed.	
<b>SARA 304 Emergency release notification</b>	
Not regulated.	
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)</b>	
Not regulated.	
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>SARA 302 Extremely hazardous substance</b>	
Not listed.	
<b>SARA 311/312 Hazardous chemical</b>	Yes
<b>Classified hazard categories</b>	Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
<b>SARA 313 (TRI reporting)</b>	
Not regulated.	

## Other federal regulations

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

Not regulated.

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

Not regulated.

### Safe Drinking Water Act (SDWA)

Not regulated.

## US state regulations

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.

## 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

\*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** 11-20-2007

**Revision date** 12-26-2019

**Version #** 04

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