SAFETY DATA SHEET

1. Identification

Product identifier **Quinapril Hydrochloride**

Other means of identification

Catalog number 1593401

Chemical name 3-Isoquinolinecarboxylic acid, 2-[2-[[1-(ethoxycarbonyl)-3-phenylpropyl]amino]-1-oxopropyl]-1,2,3,4-tetrahydro-, monohydrochloride, [3S-[2[R*(R*)],3R*]]

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

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

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 1
Specific target organ toxicity, repeated exposure Category 2 (cardiovascular system)

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement 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. Wear protective gloves/protective clothing/eye protection/face protection.

Response If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Quinapril Hydrochloride		82586-55-8	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.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

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

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed Not available.

Indication of immediate medical attention and special treatment needed 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. [Meditext 2011 and USP DI 2011]

General information 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

Suitable extinguishing media Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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 As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling 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.

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

Exposure limit values

Industrial Use

Material	Type	Value
Quinapril Hydrochloride (CAS 82586-55-8)	TWA	0.1 mg/m3

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

Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	246.2 - 266 °F (119 - 130 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Soluble.
Partition coefficient (n-octanol/water)	0.33
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Molecular formula	C25H30N2O5 . HCl
Molecular weight	474.98
Percent volatile	0.5 %

Solubility (other) Freely soluble in aqueous solvents and soluble in methanol and in acetonitrile.

10. Stability and reactivity

Reactivity No reactivity hazards known.

Chemical stability Stable at normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid None known.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

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

Inhalation Due to lack of data the classification is not possible.

Skin contact Due to lack of data the classification is not possible.

Eye contact Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics ACE inhibitors: Dizziness. Skin rash. Itching. Fever. Joint pain. Cough. Chest pain. Slow heart rate. Alteration in or loss of taste. Swelling. Bleeding. Bruising. Blood in urine or stools. Pinpoint red spots on skin. Confusion. Irregular heartbeat. Difficulty breathing. Numbness or tingling in hands, feet, or lips. Tiredness. Weakness. Heaviness of legs. Irritability. Dry mouth. Muscle cramps.

Delayed and immediate effects of exposure ACE inhibitors: Gout. Thrombocytopenia. Hyperkalemia. Electrolyte imbalance. Pancreatitis. Liver toxicity. Kidney failure. Zinc loss.

Cross sensitivity Persons sensitive to one ACE inhibitor may be sensitive to this material also.

Medical conditions aggravated by exposure ACE inhibitors: Angioedema. Active alcoholism. Severe auto-immune disease. Cerebrovascular or coronary insufficiency. Diabetes mellitus. Kidney transplant. Impaired liver or kidney function. Hyperkalemia. Bone marrow depression. Volume depletion caused by severe dietary sodium restriction or dialysis.

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

Product	Species	Test Results
Quinapril Hydrochloride (CAS 82586-55-8)		
Acute		
Oral		
LD50	Mouse	1478 mg/kg
	Rat	3541 mg/kg

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Respiratory sensitization Due to lack of data the classification is not possible.

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

Sensitization

Guinea Pig Maximization Test
Result: Non-sensitizing.
Species: Guinea pig
Organ: Skin.

Germ cell mutagenicity Based on available data, the classification criteria are not met. In vivo and in vitro mutagenicity studies were negative in a related material.

Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

100 mg/kg/day Carcinogenicity study
Result: Not carcinogenic. In female rats, there was an increased incidence of mesenteric lymph node hemangiomas and skin/subcutaneous lipomas.
Species: Rat
Test Duration: 104 weeks

75 mg/kg/day Carcinogenicity study
Result: Not carcinogenic.
Species: Mouse
Test Duration: 104 weeks

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 steriosus, and death. Prematurity can also occur. ACE inhibitors have demonstrated little or no teratogenicity in animal studies.

Reproductivity

300 mg/kg/day Reproductivity study
Result: No adverse effects on fertility or reproduction.
Species: Rat

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

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.

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

Local disposal regulations Not available.

Hazardous waste code Not regulated.

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 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

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.

US state regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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
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)

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

Issue date	01-24-2007
Revision date	04-11-2013
Version #	03
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.