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\[R^\star\],[3R^\star]]]

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/Import/Supplier/Distributor information

Company name U. S. Pharmacopoeia

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinapril Hydrochloride (CAS 82586-55-8)</td>
<td>TWA</td>
<td>0.1 mg/m3</td>
</tr>
<tr>
<td>Biological limit values</td>
<td>No biological exposure limits noted for the ingredient(s).</td>
<td></td>
</tr>
</tbody>
</table>
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

Delayed and immediate effects of exposure

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

Medical conditions aggravated by exposure

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinapril Hydrochloride (CAS 82586-55-8)</td>
<td>Mouse</td>
<td>1478 mg/kg</td>
</tr>
<tr>
<td>100 mg/kg/day Carcinogenicity study</td>
<td>Rat</td>
<td>3541 mg/kg</td>
</tr>
</tbody>
</table>

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

Reproducit
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

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

*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.