SAFETY DATA SHEETS

This SDS packet was issued with item:

078918071

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078676345 078676352 078676360 078784024 078881242 078918072 078918073 078930394

ZHEJIANG HUAHAI PHARMACEUTICAL Co., Ltd.
Xunqiao, Linhai, Zhejiang 317024, China

SECTION 1 – IDENTIFICATION

Common Name: Benazepril Hydrochloride

Formula: C24H28N2O5 . HCl

Synonym: n/f

Chemical Name: 1H-1-Benzazepine-1-acetic acid, 3-[[1-(ethoxycarbonyl)-3-phenylpropyl]amino]-2,3,4,5-tetrahydro-2-oxo, monohydrochloride, [S-(R*,R*)]-

CAS Number: 86541-74-4

RTECS Number: CX7065000

Chemical Family: n/f

Therapeutic Category: Enzyme inhibitor (angiotensin-converting) (ACE inhibitor)

SECTION 2 - INGREDIENT INFORMATION

Principle Components	Percent	Exposure Limits
Benazepril Hydrochloride	Pure Material	n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual adult oral dose of benazepril is 10 mg (base) a day initially, increased to 20 to 40 mg (base) daily.

Adverse Effects: Adverse effects may include dizziness, lightheadedness, fainting, skin rash, itching, fever, joint pain, cough, headache, diarrhea, loss of taste, unusual tiredness, and nausea. Rarely, swelling of the tongue or throat may cause life-threatening airway obstruction. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose may cause lowered blood pressure.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Inhalation:	May cause irritation. Remove to fresh air.
Eye:	May cause irritation. Flush with copious quantities of water.
Skin:	May cause irritation. Flush with copious quantities of water.
Ingestion:	May cause irritation. Flush out mouth with water. This material is rapidly but incompletely absorbed from the gastrointestinal tract. Onset of action is within one hour; effects last for 24 hours.
Medical Conditions	
Aggravated by Exposure:	Hypersensitivity to material, active alcoholism, angioedema, hyperkalemia, impaired kidney function or kidney transplant, impaired liver function, severe dietary sodium restriction, and dialysis.
Cross Sensitivity:	Persons sensitive to any ACE inhibitor may be sensitive to this material also.
Pregnancy Comments:	The therapeutic use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with serious fetal and newborn injury or death.
Pregnancy Category:	C (first trimester); D (second and third trimesters)

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Treatment of overdose consists of volume expansion for correction of hypotension and established procedures for treating dehydration and electrolyte imbalance. Benazeprilat (the active metabolite of benazepril) is slightly removable by hemodialysis. [USP DI 2003]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: >5 grams/kg

Oral Mouse: LD50: 4019 mg/kg

Irritancy Data: n/f

Target Organ(s): Cardiovascular system

Listed as a Carcinogen: **NTP:** No **IARC:** No **OSHA:** No

Other: No

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f **Upper Flammable Limit:** n/f

Auto-Ignition Temperature: n/f **Lower Flammable Limit:** n/f

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to moisture, light, and heat.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.

Stable: yes **Hazardous Polymerization:** No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

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. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a refrigerator.

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Ventilation: Recommended.

Gloves: Rubber

Eye Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: White to off-white crystalline powder; slight odor.

Melting Point: 183° C

Solubility: Soluble in water,

Vapor Density: n/f

Boiling Point: n/f **Evaporation Rate:** n/f

Specific Gravity: n/f **Reactivity in Water:** n/f

Vapor Pressure: n/f **% Volatile by Volume:** n/f

09/12/2012

SAFETY DATA SHEET

OSHA's Hazard Communication Standard 2012

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier	
Product name	BENAZEPRIL HYDROCHLORIDE TABLETS
Other means of identification	Not available
Synonym(s)	Benazepril Hydrochloride Tablets, USP, 5mg Benazepril Hydrochloride Tablets, USP, 10mg Benazepril Hydrochloride Tablets, USP, 20mg Benazepril Hydrochloride Tablets, USP, 40mg
UN-Number	n/a
Recommended use	Medicinal Product
	This safety data sheet is to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Recommended restrictions	No other uses are advised
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	Zhejiang Huahai Pharmaceutical Co Ltd
	Xunqiao, Linhai, Zhejiang 317024, China
Normal business hour	Phone No.: 008657685016474
Email address	leikewei@huahaipharm.com
Emergency telephone number	008657685016474

2. Hazards Identification

Classified hazards

Physical hazards:	Not classified.	
Health hazards:	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 2 (cardiovascular system)
OSHA defined hazards:	Not classified.	

Label elements

INDICATIONS AND USAGE

Benazepril hydrochloride is an angiotensin-converting enzyme (ACE) inhibitor indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

WARNINGS AND PRECAUTIONS

- Angioedema: Discontinue benazepril hydrochloride and treat appropriately.
- Monitor renal function periodically.

- Monitor blood pressure after initiation.
- Hyperkalemia: Monitor serum potassium periodically.
- Hepatic toxicity: Monitor for jaundice or signs of liver failure.

Hazard(s) not otherwise classified (HNOC)

Available hazard identification for Active Pharmaceutical Ingredient (API) alone:

Label elements:

Signal word: Warning

Hazard statement: Suspected of damaging 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: I Dispose of contents/container to an approved disposal site.

3. Composition/Information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
BENAZEPRIL HYDROCHLORIDE		86541-74-4	1-20
LACTOSE		10039-26-6	40-70
MICROCRYSTALLINE CELLULOSE		9004-34-6	10-40
STARCH		9005-25-8	<10
Other components below reportable levels			<10

4. First aid measures

Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention 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	Use carbon dioxide, dry chemical, or water spray.
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	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.
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.
Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and storage

Precautions for safe handling

Precautions for safe handling	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

	Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for safe storage, including any incompatibilities	Store as directed by product packaging.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Benazepril Hydrochloride (CAS 86541-74-4)	TWA	0.02 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.
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	
Physical state	Solid.
Form	Tablet.
Color	

Strengths(mg)	**Color**
5	white
10	red
20	grey
40	blue

Odor	Slight odor.
Odor threshold	Not available.
pH	Not available.
Melting point/range	Not available.
Boling point/boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability limits in air	Not available.
Flammability limit – upper (%)	Not available.
Flammability limit – lower (%)	Not available.
Explosive limit – lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Specific gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient: (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Product Description	
Strengths	**Product Description**
5 mg	Round, white film coated tablet, debossed “S” on one side and “341” on the other side.
10 mg	Round, red film coated tablet, debossed “S ” on one side and “342” on

	the other side.
20 mg	Round, grey film coated tablet, debossed “S ” on one side and “343” on the other side.
40 mg	Round, blue film coated tablet, debossed “S ” on one side and “344” on the other side.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reaction	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible material	As a precautionary measure, keep away from strong oxidizers
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.	
Acute toxicity	Based on available data, the classification criteria are not met.	
Components	**Species**	**Test Results**
Benazepril Hydrochloride (CAS 86541-74-4)		
Oral		
LD50	Mouse	4019 mg/kg
	Rat	> 5 g/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Acute		
Oral		
LD50	Rat	> 5000 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 or skin sensitization		

Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
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. A related material has not caused cancer in animal studies.
Reproductive toxicity	Suspected of damaging 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	500 mg/kg/day Reproductive performance test Result: No adverse effects. Species: Rat Reproductive study Result: No embryotoxicity, fetotoxicity, or birth defects at 3 times the maximum human recommended dose by weight. Maximum human recommended dose of 80 mg/kg. Species: Rabbit Reproductive study Result: No embryotoxicity, fetotoxicity, or birth defects at 300 times the maximum human recommended dose by weight. Maximum human recommended dose: 80 mg/kg. Species: Rat Reproductive study Result: No embryotoxicity, fetotoxicity, or birth defects at 90 times the maximum human recommended dose by weight. Maximum human recommended dose: 80 mg/kg. Species: Mouse
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.
Further information	See package insert.

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	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
Local disposal regulations	Dispose in accordance with all applicable regulations.
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.	
IMDG	
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.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
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	Yes
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)

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

Issue date 17.10.2015

Revision date 17.10.2015

Version # 005A

Reference 1) USP Benazepril Hydrochloride SDS

2) GREENSTONE Benazepril Hydrochloride Tablets MSDS
3) HUAHAI Benazepril Hydrochloride Tablets MSDS

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet