



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 2.1

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Accuretic Tablets

Trade Name: ACCURETIC
Synonyms: Quinapril/HCTZ Tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antihypertensive

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydrochlorothiazide	58-93-5	200-403-3	6.1-12.1
Magnesium stearate	557-04-0	209-150-3	*
Quinapril hydrochloride	82586-55-8	Not listed	10.5

Ingredient	CAS Number	EU EINECS List	%
Magnesium carbonate	39409-82-0	Not listed	*
Lactose hydrous	64044-51-5	Not listed	*
Povidone	9003-39-8	Not listed	*
Crospovidone	9003-39-8	Not listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Pink tablets
Signal Word: WARNING

Statement of Hazard: May cause adverse effects on fetal development

Additional Hazard Information:

Short Term: Not a skin sensitizer, Not acutely toxic (based on animal data). In humans, the use of drugs in this class (ACE inhibitors) can cause fetal and neonatal toxicity, including low blood pressure and kidney failure, when they are taken during the second and third trimesters of pregnancy. Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys, liver, gastrointestinal system, heart, and blood.

Long Term:

Known Clinical Effects: Effects reported during clinical use include dizziness, headache, lethargy, changes in blood pressure, nausea, and abdominal pain.

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EU Indication of danger: Toxic to Reproduction; Category 3

EU Hazard Symbols:



EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash the affected area with soap and water. Seek medical attention if unusual symptoms occur. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Ingestion: In the event of swallowing this material, dilute with large quantities of water or milk. Get medical attention.

Inhalation: Remove to fresh air. If discomfort persists, get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: No data available

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards: Not determined

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Use appropriate ventilation.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hydrochlorothiazide

Pfizer OEL TWA-8 Hr: 0.25 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Quinapril hydrochloride

Pfizer OEL TWA-8 Hr: 0.1 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for Quinapril hydrochloride. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	Pink
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Polymerization: Will not occur

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Hydrochlorothiazide

Rat Oral LD 50 2750 mg/kg
Mouse Oral LD 50 2830 mg/kg
Rat Intravenous LD 50 990 mg/kg
Dog Intravenous LD 50 250 mg/kg

Quinapril hydrochloride

Rat Oral LD50 3541 mg/kg
Mouse Oral LD50 1478 mg/kg
Rat IV LD50 107 mg/kg

Povidone

Rat Oral LD50 100 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Quinapril hydrochloride

Skin Sensitization - GPMT Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Hydrochlorothiazide

30 Day(s) Rat Oral 1 g/kg/day LOAEL Blood
13 Week(s) Mouse Oral 12,500 ppm LOAEL Bladder
9 Month(s) Dog Oral 50 mg/kg/day LOAEL Endocrine system
1 Year(s) Rat Oral 2000 ppm LOAEL Kidney
2 Year(s) Rat Oral 250 ppm LOAEL Kidney

Quinapril hydrochloride

13 Week(s) Rat Oral 50 mg/kg/day LOAEL Gastrointestinal System, Blood, Heart, Kidney
13 Week(s) Dog Oral 25 mg/kg/day NOAEL Kidney, Blood, Liver, Gastrointestinal system
52 Week(s) Rat Oral 10 mg/kg/day LOAEL Kidney
52 Week(s) Dog Oral 10 mg/kg/day NOAEL Blood, Gastrointestinal system, Heart, Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Hydrochlorothiazide

Reproductive & Fertility Rat Oral 1000 mg/kg LOAEL Maternal toxicity
Reproductive & Fertility Mouse Oral 3000 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOEL Not Teratogenic
Embryo / Fetal Development Mouse Oral 3000 mg/kg/day NOEL Not Teratogenic

Quinapril hydrochloride

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Peri-/Postnatal Development Rat Oral 150 mg/kg/day NOAEL No effects at maximum dose
Reproductive & Fertility Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose
Prenatal & Postnatal Development Rat Oral 300 mg/kg/day NOAEL Not Teratogenic, No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Hydrochlorothiazide

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Dominant Lethal Assay *Drosophila* Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Positive

Quinapril hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
In Vivo Cytogenetics Rat Bone Marrow Negative
In Vivo Micronucleus Mouse Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Hydrochlorothiazide

2 Year(s) Rat Oral 2000 ppm NOAEL Not carcinogenic
2 Year(s) Female Mouse Oral 5000 ppm NOAEL Not carcinogenic
2 Year(s) Male Mouse Oral 5000 ppm LOAEL Malignant tumors, Liver

Quinapril hydrochloride

104 Week(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic
104 Week(s) Mouse Oral 75 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Hydrochlorothiazide

IARC: Group 3

Povidone

IARC: Group 3

Crospovidone

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction; Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause adverse effects on fetal development

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Hydrochlorothiazide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-403-3
Magnesium carbonate	
Australia (AICS):	Present
Lactose hydrous	
Australia (AICS):	Present
Povidone	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

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Crospovidone

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):

XU
Present

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet