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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
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
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Accuretic Tablets

   Trade Name: ACCURETIC; ACCUZIDE
   Synonyms: Quinapril and Hydrochlorothiazide Tablets
   Chemical Family: Mixture
   Intended Use: Pharmaceutical product used as antihypertensive

2. HAZARDS IDENTIFICATION

Appearance: Pink tablets
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.

Additional Hazard Information:
   Short Term: Antihypertensive drug: has blood pressure-lowering properties
   Accidental ingestion may cause effects similar to those seen in clinical use. 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.

   Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on
   kidneys, liver, gastrointestinal system, heart, and blood.

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

   EU Indication of danger: Toxic to Reproduction: Category 3

EU Hazard Symbols: Xn

EU Risk Phrases: R63 - Possible risk of harm to the unborn child.

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quinapril hydrochloride</td>
<td>82586-55-8</td>
<td>Not Listed</td>
<td>Repr.Cat.3;R63</td>
<td>10.5</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5</td>
<td>200-403-3</td>
<td>Not Listed</td>
<td>6.1-12.1</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose hydrous</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium carbonate</td>
<td>39409-82-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.
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.

7. HANDLING AND STORAGE

General 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 thoroughly after handling. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Quinapril hydrochloride
Pfizer OEL TWA-8 Hr: 100µg/m³
Hydrochlorothiazide
Pfizer OEL TWA-8 Hr: 250µg/m³
Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³


Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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
Molecular Formula: Mixture
Color: Pink
Molecular Weight: Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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 LD50 2750 mg/kg
Mouse Oral LD50 2830 mg/kg
Rat Intravenous LD50 990 mg/kg
Dog Intravenous LD50 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
11. TOXICOLOGICAL INFORMATION

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
- 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
11. TOXICOLOGICAL INFORMATION

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 (Not Classifiable)

Povidone
IARC: Group 3 (Not Classifiable)

Crospovidone
IARC: Group 3 (Not Classifiable)

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

Waste Treatment Methods: 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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.
15. REGULATORY INFORMATION

OSHA Label:
WARNING
Suspected of damaging the unborn child.

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:
- EU EINECS/ELINCS List: 200-403-3

Lactose hydrous
- Australia (AICS): Present

Magnesium stearate
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-150-3

Magnesium carbonate
- Australia (AICS): Present

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

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information.

Reasons for Revision:
Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information. Updated Section 7 - Handling and Storage. Updated Section 4 - First Aid Measures.
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet