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

Product Identifier

<table>
<thead>
<tr>
<th>Material Name:</th>
<th>Accuretic Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>Accuretic; Accuzide; Acuilix; Aquinaretic; Accumax; Accupro; Acupil H; Hemokvin Plus</td>
</tr>
<tr>
<td>Synonyms:</td>
<td>Quinapril and Hydrochlorothiazide Tablets</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

| Intended Use: | Pharmaceutical product used as antihypertensive |

Details of the Supplier of the Safety Data Sheet

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Pharmaceuticals Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Ltd</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>Emergency telephone number:</td>
<td>+00 44 (0)1304 616161</td>
</tr>
<tr>
<td>CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number:</td>
</tr>
<tr>
<td>Contact E-Mail: <a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td>International CHEMTREC (24 hours): +1-703-527-3887</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

<table>
<thead>
<tr>
<th>GHS - Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Toxicity: Category 2</td>
</tr>
<tr>
<td>EU Classification:</td>
</tr>
<tr>
<td>EU Indication of danger: Toxic to Reproduction: Category 3</td>
</tr>
<tr>
<td>EU Risk Phrases:</td>
</tr>
<tr>
<td>R63 - Possible risk of harm to the unborn child.</td>
</tr>
</tbody>
</table>

Label Elements

<table>
<thead>
<tr>
<th>Signal Word:</th>
<th>Warning</th>
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</thead>
<tbody>
<tr>
<td>Hazard Statements:</td>
<td>H361d - Suspected of damaging the unborn child</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precautionary Statements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>P201 - Obtain special instructions before use</td>
</tr>
<tr>
<td>P281 - Use personal protective equipment as required</td>
</tr>
<tr>
<td>P308 + P313 - IF exposed or concerned: Get medical attention/advice</td>
</tr>
<tr>
<td>P405 - Store locked up</td>
</tr>
</tbody>
</table>
Other Hazards
Australian Hazard Classification (NOHSC):

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>GHS 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>Repr.2 (H361d)</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>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>Not Listed *</td>
<td></td>
</tr>
<tr>
<td>Lactose hydrous</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed *</td>
<td></td>
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<tr>
<td>Magnesium carbonate</td>
<td>39409-82-0</td>
<td>Not Listed</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>Not Listed *</td>
<td></td>
</tr>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not Listed</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. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.
Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

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

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 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Quinapril hydrochloride
- Protective Clothing: 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.
- Exposure 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.

Hydrochlorothiazide
- Protective Clothing: Impervious gloves are 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.
- Exposure 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.

Magnesium stearate
- Protective Clothing: 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.
- Exposure 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
<th>Color:</th>
<th>Pink</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility: | No data available |
| Water Solubility: | No data available |
| pH: | No data available |
| Melting/Freezing Point (°C): | No data available |
| Boiling Point (°C): | No data available |
| Partition Coefficient: (Method, pH, Endpoint, Value): | No data available |

**Hydrochlorothiazide**
- No data available
- Predicted 7 Log P 3.41

**Povidone**
- No data available

**Magnesium carbonate**
- No data available

**Lactose hydrous**
- No data available

**Crosподive**
- No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Magnesium stearate

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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 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.

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

Hydrochlorothiazide

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>2750 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>2830mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intravenous</td>
<td>LD 50</td>
<td>990mg/kg</td>
</tr>
<tr>
<td>Dog</td>
<td>Intravenous</td>
<td>LD 50</td>
<td>250mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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
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
11. TOXICOLOGICAL INFORMATION

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 (Not Classifiable)

Povidone
IARC:  Group 3 (Not Classifiable)

Crosopovidone
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.

Toxicity:  No data available

Persistence and Degradability:  No data available

Bio-accumulative Potential:
Quinapril hydrochloride
Predicted  7  Log P  3.41

Mobility in Soil:  No data available
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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Canada - WHMIS: Classifications**

WHMIS hazard class:

Class D, Division 2, Subdivision A

---

Quinapril hydrochloride

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
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</table>

Hydrochlorothiazide

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Status</th>
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<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
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<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>200-403-3</td>
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Lactose hydrous

<table>
<thead>
<tr>
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<th>Status</th>
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</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>Not Listed</td>
<td>Present</td>
</tr>
<tr>
<td>Magnesium carbonate</td>
<td>Not Listed</td>
<td>Present</td>
</tr>
<tr>
<td>Povidone</td>
<td>Not Listed</td>
<td>Present</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>Not Listed</td>
<td>Present</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 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 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 04-Nov-2014

Prepared by: Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations
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