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

Material Name: **Accupril® (Quinapril Hydrochloride) Tablets**

| Trade Name: ACCUPRIL | Pfizer Ltd
| Chemical Family: Mixture | Ramsgate Road
| Intended Use: Pharmaceutical product used as Antihypertensive | 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

2. HAZARDS IDENTIFICATION

**Appearance:**
- 5 mg: Brown, film-coated, elliptical tablets
- 10 mg: Brown, film-coated, triangular tablets
- 20 mg: Brown, film-coated, round tablets
- 40 mg: Brown, film-coated, elliptical 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
- **Long Term:** 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.

**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:**

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

Australian Hazard Classification (NOHSC):
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>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>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>5.4 - 10.8</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>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</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>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>Synthetic red iron oxide</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Xn; R22</td>
<td>*</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Candelilla wax</td>
<td>8006-44-8</td>
<td>232-347-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</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.
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).

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

Magnesium carbonate
Estonia OEL - TWA Listed

Titanium dioxide
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA Listed
Austria OEL - MAKs Listed
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Denmark OEL - TWA Listed
Estonia OEL - TWA Listed
France OEL - TWA Listed
Germany (DFG) - MAK = 1.5 mg/m³ MAK
Greece OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA
= 4 mg/m³ TWA
Latvia OEL - TWA Listed
Lithuania OEL - TWA Listed
Netherlands OEL - TWA Listed
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
Poland OEL - TWA Listed
Portugal OEL - TWA Listed
Romania OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs = 5 mg/m³ LLV

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
Belgium OEL - TWA Listed
Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs = 5 mg/m³ LLV

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


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.

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.
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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Film-coated tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Brown</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

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)
MATERIAL SAFETY DATA SHEET

Material Name: Accupril® (Quinapril Hydrochloride) Tablets
Revision date: 19-Jun-2008

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)

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))

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)

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))

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: See below

Crosopovidone
IARC: Group 3 (Not Classifiable)

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Present

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. 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

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.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Lactose hydrous
Australia (AICS): Present

Magnesium carbonate
Australia (AICS): Present

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

Candelilla wax
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 232-347-0

Gelatin
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS/ELINCS List 232-554-6

Titanium dioxide
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 236-675-5
Magnesium stearate

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

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 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. 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

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