SAFETY DATA SHEET

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

Product Identifier

Material Name: Accupril® (Quinapril Hydrochloride) Tablets

Trade Name: Accupril; Accupro; Acuitel; Aquinafil; Accumax; Accupron; Acupil; Accupri; Conan; Hemokvin; Acuprel

Chemical Family: Mixture

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3

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

Label Elements

Signal Word: Warning

Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
SAFETY DATA SHEET

Material Name: Accupril® (Quinapril Hydrochloride) Tablets
Revision date: 04-Nov-2014
Version: 3.0

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>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>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>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>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>
<tr>
<td>Synthetic red iron oxide</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</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>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>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</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.
SAFETY DATA SHEET

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

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
SAFETY DATA SHEET

Material Name: Accupril® (Quinapril Hydrochloride) Tablets
Revision date: 04-Nov-2014

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

Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m³
ACGIH OELs - Notice of Intended Changes Listed
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Denmark OEL - TWA 6 mg/m³
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 10.0 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 6 mg/m³
5 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³


Exposure Controls

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

Physical State: Film-coated tablets  
Color: Brown  
Odor: No data available.  
Odor Threshold: No data available.  
Molecular Formula: Mixture  
Molecular Weight: Mixture  
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)  
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.
10. STABILITY AND REACTIVITY

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

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.

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

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

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

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

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
11. TOXICOLOGICAL INFORMATION

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

Quinapril hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella , E. coli  Negative
\textit{In Vitro} Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Negative
\textit{In Vivo} Cytogenetics  Rat Bone Marrow  Negative
\textit{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

Crospovidone
IARC:  Group 3 (Not Classifiable)

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

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:
Partition Coefficient: (Method, pH, Endpoint, Value)
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

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Crosovidone

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Synthetic red iron oxide

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Candelilla wax

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-347-0

Magnesium carbonate

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
15. REGULATORY INFORMATION

EU EINECS/ELINCS List
Not Listed

Lactose hydrous
CERCLA/SARA 313 Emission reporting
Not Listed
California Proposition 65
Not Listed
Australia (AICS):
Pfizer proprietary drug development information.
REACH - Annex IV - Exemptions from the obligations of Register:
Present
EU EINECS/ELINCS List
Not Listed

Gelatin
CERCLA/SARA 313 Emission reporting
Not Listed
California Proposition 65
Not Listed
Inventory - United States TSCA - Sect. 8(b)
Present
Australia (AICS):
Present
EU EINECS/ELINCS List
232-554-6

Titanium dioxide
CERCLA/SARA 313 Emission reporting
Not Listed
California Proposition 65
carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)
Present
Australia (AICS):
Present
EU EINECS/ELINCS List
236-675-5

Magnesium stearate
CERCLA/SARA 313 Emission reporting
Not Listed
California Proposition 65
Not Listed
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 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.

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