



# MATERIAL SAFETY DATA SHEET

Revision date: 19-Jun-2008

Version: 2.4

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## 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

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

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

Trade Name:	ACCUPRIL
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antihypertensive

## 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:**  
Xn



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

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

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## 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Quinapril hydrochloride	82586-55-8	Not listed	Repr.Cat.3;R63	5.4 - 10.8
Magnesium carbonate	39409-82-0	Not listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lactose hydrous	64044-51-5	Not listed	Not Listed	*
Synthetic red iron oxide	NOT ASSIGNED	Not listed	Xn;R22	*
Crospovidone	9003-39-8	Not listed	Not Listed	*
Candelilla wax	8006-44-8	232-347-0	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*

**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.

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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.

### 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<b>Quinapril hydrochloride</b>		
Pfizer OEL TWA-8 Hr:	100µg/m <sup>3</sup>	
<b>Magnesium carbonate</b>		
Estonia OEL - TWA	Listed	
<b>Titanium dioxide</b>		
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	
Australia TWA	= 10 mg/m <sup>3</sup> TWA	
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/m <sup>3</sup> MAK	
Greece OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA = 4 mg/m <sup>3</sup> TWA	
Latvia OEL - TWA	Listed	
Lithuania OEL - TWA	Listed	
Netherlands OEL - TWA	Listed	
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA	total
Poland OEL - TWA	Listed	
Portugal OEL - TWA	Listed	
Romania OEL - TWA	Listed	
Spain OEL - TWA	Listed	
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	
<b>Magnesium stearate</b>		
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m <sup>3</sup> TWA	
Belgium OEL - TWA	Listed	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA	except lead stearate
Lithuania OEL - TWA	Listed	
Portugal OEL - TWA	Listed	
Spain OEL - TWA	Listed	
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	

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

<b>Analytical Method:</b>	Analytical method available for Quinapril hydrochloride. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.

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**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:

<b>Physical State:</b>	Film-coated tablets	<b>Color:</b>	Brown
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**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)**

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### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

### Quinapril hydrochloride

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

### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 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

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

#### Quinapril hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Cytogenetics	Rat Bone Marrow	Negative
<i>In Vivo</i> 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

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**Carcinogen Status:** See below

**Crospovidone**  
**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.

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## 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



<b>Lactose hydrous</b>	
Australia (AICS):	Present
<b>Magnesium carbonate</b>	
Australia (AICS):	Present
<b>Crospovidone</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
<b>Candelilla wax</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-347-0
<b>Gelatin</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6
<b>Titanium dioxide</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

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### 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**