



# MATERIAL SAFETY DATA SHEET

Revision date: 13-Feb-2012

Version: 3.0

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

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### 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.  
Hazardous Substance. Non-Dangerous Goods.

### Australian Hazard Classification (NOHSC):

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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	EU Classification	%
Quinapril hydrochloride	82586-55-8	Not Listed	Repr.Cat.3;R63	10.5
Hydrochlorothiazide	58-93-5	200-403-3	Not Listed	6.1-12.1
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose hydrous	64044-51-5	Not Listed	Not Listed	*
Magnesium carbonate	39409-82-0	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Crospovidone	9003-39-8	Not Listed	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.

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

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### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	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.
<b>Storage Conditions:</b>	Store as directed by product packaging.

### 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>Hydrochlorothiazide</b>	
Pfizer OEL TWA-8 Hr:	250µg/m <sup>3</sup>
<b>Magnesium stearate</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

<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>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<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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## 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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Pink
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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 LD 50 2750 mg/kg  
Mouse Oral LD 50 2830 mg/kg  
Rat Intravenous LD 50 990 mg/kg  
Dog Intravenous LD 50 250 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/m<sup>3</sup>

**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

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## 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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Positive
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Dominant Lethal Assay	<i>Drosophila</i>	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive

#### 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))

#### 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

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### 11. TOXICOLOGICAL INFORMATION

<b>Carcinogen Status:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below
<b>Hydrochlorothiazide IARC:</b>	Group 3 (Not Classifiable)
<b>Povidone IARC:</b>	Group 3 (Not Classifiable)
<b>Crospovidone IARC:</b>	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

<b>EU Symbol:</b>	Xn
<b>EU Indication of danger:</b>	Toxic to Reproduction: Category 3
<b>EU Risk Phrases:</b>	R63 - Possible risk of harm to the unborn child.
	S36/37 - Wear suitable protective clothing and gloves.

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## 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:	Schedule 4
EU EINECS/ELINCS List	200-403-3

### Lactose hydrous

Australia (AICS):	Present
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### 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
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### 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.

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**Prepared by:**

Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**