



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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**New York, New York 10017**  
**1-212-573-2222**

**Pfizer Ltd**  
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**United Kingdom**  
**+00 44 (0)1304 616161**

**Emergency telephone number:**  
**CHEMTREC (24 hours): 1-800-424-9300**

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

**Material Name: Diltiazem Hydrochloride Capsules - 180 and 240 mg**

**Trade Name:** Dilzem  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used for angina high blood pressure (hypertension)

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Diltiazem Hydrochloride	33286-22-5	251-443-3	43.65
Talc (non-asbestiform)	14807-96-6	238-877-9	28.1
Sucrose	57-50-1	200-334-9	9.1
Corn Starch	9005-25-8	232-679-6	1.5
Fumaric acid	110-17-8	203-743-0	10.9

Ingredient	CAS Number	EU EINECS List	%
Poly (ethylacrylate, methylmethacrylate, trimethylammonioethylmethacrylatechloride) 1:2:0:1	Not assigned	Not listed	*
Poly (ethylacrylate, methylmethacrylate, trimethylammonioethylmethacrylatechloride) 1:2:0:2	Not assigned	Not listed	*
Purified water	7732-18-5	231-791-2	*
Povidone	9003-39-8	Not listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Capsules  
**Signal Word:** WARNING

**Statement of Hazard:** May be harmful if swallowed.  
May cause harm to the unborn child.

**Additional Hazard Information:**

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**Short Term:**

May cause eye irritation (based on components) . Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

**Long Term:**

Animal studies indicate that this material may cause adverse effects on the fetus.

**Known Clinical Effects:**

Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.

**EU Indication of danger:**

Harmful  
Toxic to reproduction, Category 2

**EU Hazard Symbols:**



**EU Risk Phrases:**

R22 - Also harmful if swallowed  
R61 - May cause harm to the unborn child.

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

### 4. FIRST AID MEASURES

**Eye Contact:**

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**

Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:**

Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:**

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### 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:**

Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:**

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

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**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:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Diltiazem Hydrochloride

Pfizer OEL TWA-8 Hr: 1.0 mg/m<sup>3</sup>

### Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA  
Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

### Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Corn Starch

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

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

**Analytical Method:** Analytical method available for Diltiazem Hydrochloride. Contact Pfizer Inc for further information.

**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.

### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.  
**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

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**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>	Capsule	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

#### **Diltiazem Hydrochloride**

Rat	Oral	LD50	560 mg/kg
Rat	Intravenous	LD50	38 mg/kg
Rat	Subcutaneous	LD50	520 mg/kg
Mouse	Oral	LD50	508 mg/kg
Mouse	Intravenous	LD50	58 mg/kg

#### **Talc (non-asbestiform)**

Rat	Oral	LD50	> 1600 mg/kg
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#### **Sucrose**

Rat	Oral	LD50	29.7 g/kg
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#### **Povidone**

Rat	Oral	LD50	100 g/kg
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### Irritation / Sensitization: (Study Type, Species, Severity)

#### **Fumaric acid**

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### **Diltiazem Hydrochloride**

Reproductive & Fertility	Rat	Oral	100 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Mouse	Oral	25 mg/kg	LOAEL	Embryotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	80 mg/kg	LOAEL	Embryotoxicity, Teratogenic

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Embryo / Fetal Development Rabbit Intraperitoneal 125 mg/kg LOAEL Fetotoxicity, Teratogenic

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

### Diltiazem Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

*In Vivo* Mammalian Cell Mutagenicity Negative

*In Vitro* Mammalian Cell Mutagenicity Negative

## Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Diltiazem Hydrochloride

21 Month(s) Mouse Oral 30 mg/kg/day NOAEL Not carcinogenic

24 Month(s) Rat Oral 100 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

### Talc (non-asbestiform)

#### IARC:

Group 3

### Povidone

#### IARC:

Group 3

## 12. ECOLOGICAL INFORMATION

### Environmental Overview:

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

### Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

### EU Symbol:

T

### EU Indication of danger:

Harmful

Toxic to reproduction, Category 2

### EU Risk Phrases:

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R22 - Also harmful if swallowed  
R61 - May cause harm to the unborn child.

## EU Safety Phrases:

S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

## OSHA Label:

WARNING

May be harmful if swallowed.

May cause harm to the unborn child.

## Canada - WHMIS: Classifications

### WHMIS hazard class:

D2a very toxic materials



### Diltiazem Hydrochloride

California Proposition 65

Australia (AICS):

EU EINECS List

Listed - Developmental Toxicity

Present

251-443-3

### Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

238-877-9

### Sucrose

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

200-334-9

### Purified water

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

231-791-2

### Corn Starch

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

XU

Present

232-679-6

### Povidone

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

XU

Present

### Fumaric acid

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CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	= 5000 lb final RQ
Australia (AICS):	Present
EU EINECS List	Present
	203-743-0

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**