



# 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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Sandwich, Kent  
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+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 Powder for Injection

Trade Name: Dilzem  
Chemical Family: Mixture  
Intended Use: Pharmaceutical active used as antihypertensive, heart rhythm control (anti-arrhythmic)

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient              | CAS Number | EU EINECS List | %     |
|-------------------------|------------|----------------|-------|
| Diltiazem Hydrochloride | 33286-22-5 | 251-443-3      | 14.25 |

| Ingredient   | CAS Number | EU EINECS List | %   |
|--------------|------------|----------------|-----|
| Mannitol     | 69-65-8    | 200-711-8      | *   |
| Nitrogen, NF | 7727-37-9  | 231-783-9      | ### |

### Additional Information:

\* Proprietary  
### as required  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

Appearance: Lyophilised powder  
Signal Word: WARNING

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

### Additional Hazard Information:

Short Term: 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: Toxic to reproduction, Category 2

EU Hazard Symbols:

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### EU Risk Phrases:

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

|                      |  |
|----------------------|--|
| <b>Eye Contact:</b>  | Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.                        |
| <b>Skin Contact:</b> | Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.                       |
| <b>Ingestion:</b>    | Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |
| <b>Inhalation:</b>   | Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.   |

## 5. FIRE FIGHTING MEASURES

|                                       |   |
|---------------------------------------|---|
| <b>Extinguishing Media:</b>           | Use carbon dioxide, dry chemical, or water spray.   |
| <b>Hazardous Combustion Products:</b> | Formation of toxic gases is possible during heating or fire.  |
| <b>Fire Fighting Procedures:</b>      | During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. |
| <b>Fire / Explosion Hazards:</b>      | Fine particles (such as dust and mists) may fuel fires/explosions.  |

## 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

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|                            |  |
|----------------------------|--|
| <b>General Handling:</b>   | Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Minimize dust generation and accumulation. Use with adequate ventilation. |
| <b>Storage Conditions:</b> | 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>

**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. Local and general ventilation should be used as necessary, when handling this material in bulk.

#### Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** None required with normal use of this material. Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material. Clean up spills immediately.

**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:

Lyophilized powder

#### Color:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

### 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:

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

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Mouse Intravenous LD50 58 mg/kg

### **Mannitol**

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

### **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 |
| 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.

## **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:**

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**EU Indication of danger:** Toxic to reproduction, Category 2

**EU Risk Phrases:**  
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



#### Mannitol

|   |           |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present   |
| Australia (AICS):                           | Present   |
| EU EINECS List                              | 200-711-8 |

#### Nitrogen, NF

|   |           |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present   |
| Australia (AICS):                           | Present   |
| EU EINECS List                              | 231-783-9 |

#### Diltiazem Hydrochloride

|                           |                                 |
|---------------------------|---------------------------------|
| California Proposition 65 | Listed - Developmental Toxicity |
| Australia (AICS):         | Present                         |
| EU EINECS List            | 251-443-3                       |

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. 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

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.

**End of Safety Data Sheet**

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