



# SAFETY DATA SHEET

Revision date 21-May-2023

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
**Product Code(s)** PZ03416  
**Trade Name:** Not applicable  
**Chemical Family:** Calcium channel blocker

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product for the treatment of high blood pressure (hypertension) angina

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Acute toxicity - Oral** Category 4 - (H302)  
**Reproductive toxicity** Category 1B - (H360D)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements** H302 - Harmful if swallowed  
H360D - May damage the unborn child

**Precautionary Statements** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P280 - Wear protective gloves and protective clothing  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P308 + P313 - IF exposed or concerned: Get medical attention/advice

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P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



## 2.3. Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### 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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Substances Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Diltiazem Hydrochloride (CAS #: 33286-22-5)	57		251-443-3	Acute Tox.4 (H302) Repr.1B (H360D)	Not Listed	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Mannitol (CAS #: 69-65-8)	43	-	200-711-8	Not classified as hazardous	Not Listed	No data available	No data available

### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate  
No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Diltiazem Hydrochloride	560	No data available	No data available	No data available	No data available

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
33286-22-5					
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available

## Additional information

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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

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## 6.1. Personal precautions, protective equipment and emergency procedures

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

**For emergency responders** Use personal protection recommended in Section 8.

## 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

## 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Minimize dust generation and accumulation. Avoid breathing dust. 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical product for the treatment of high blood pressure (hypertension).

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Diltiazem Hydrochloride**

Pfizer OEL TWA-8 Hr: 70 µg/m<sup>3</sup>

#### **Mannitol**

Russia

MAC: 10 mg/m<sup>3</sup>

### 8.2. 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

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airborne contamination levels below the exposure limits listed above in this section.

<b>Environmental exposure controls</b>	No information available.
<b>Personal protective equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
<b>Eye/face protection</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
<b>Hand protection</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
<b>Skin and body protection</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
<b>Respiratory protection</b>	Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Lyophilized powder
<b>Color</b>	Off-white
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture
<b>Property</b>	<b>Values</b>
<b>pH</b>	No data available
<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available

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<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## 9.2. Other information

No information available

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

**Reactivity** No data available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

### Explosion data

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

### 10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<b>Short term</b>	May be harmful if swallowed (based on animal data) 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.
<b>Long Term:</b>	Animal studies have shown a potential to cause adverse effects on the fetus.
<b>Known Clinical Effects:</b>	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.
<b>Acute toxicity</b>	Classification is based on mixture calculation methods based on component data
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Classification is based on mixture calculation methods based on component data.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.

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**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

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

### **Diltiazem Hydrochloride**

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

### **Mannitol**

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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Diltiazem Hydrochloride	= 560 mg/kg ( Rat )	-	-
Mannitol	= 13500 mg/kg ( Rat )	-	-

## **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

### **Diltiazem Hydrochloride**

1 Month(s) Rat Oral 100 mg/kg/day NOAEL Liver, Blood, Heart  
1 Month(s) Dog Oral 5 mg/kg/day NOAEL Kidney, Heart  
6 Month(s) Dog Oral 10 mg/kg/day LOAEL Heart, Liver, Cardiovascular system  
1 Year(s) Dog Oral 5 mg/kg/day LOAEL Cardiovascular system, Heart  
6 Month(s) Rat Oral 10 mg/kg/day NOAEL None identified

## **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

### **Diltiazem Hydrochloride**

Reproductive & Fertility Rat Oral 50 mg/kg/day NOAEL Fertility  
Embryo / Fetal Development Mouse Oral 25 mg/kg/day LOAEL Embryotoxicity  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Fetotoxicity  
Embryo / Fetal Development Rabbit Intraperitoneal 6.3 mg/kg/day LOAEL Fetotoxicity, Teratogenic  
Embryo / Fetal Development Rabbit Oral 17.5 mg/kg/day NOAEL 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

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

### **11.2.2. Other information**

**Other adverse effects** No information available.

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## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

### 12.1. Toxicity

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 wastewater 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.

## Section 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.**

**UN number:** Not applicable

**UN proper shipping name:** Not applicable

**Transport hazard class(es):** Not applicable

**Packing group:** Not applicable



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**Environmental Hazard(s):** Not applicable

**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Diltiazem Hydrochloride

**CERCLA/SARA Section 313 de minimus %**

Not Listed

**California Proposition 65**

developmental toxicity 2/27/2001

**EINECS**

251-443-3

Mannitol

**CERCLA/SARA Section 313 de minimus %**

Not Listed

**California Proposition 65**

Not Listed

**TSCA**

Present

**EINECS**

200-711-8

**AICS**

Present

### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### **Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### **Persistent Organic Pollutants**

Not applicable

### **Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

### **Full text of H-Statements referred to under section 3**

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

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**Data Sources:** Pfizer proprietary drug development information.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 21-May-2023

**Prepared By** Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this 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.**