



# SAFETY DATA SHEET

Revision date 13-Jun-2025

Version 3

Page 1 / 11

## 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

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**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)

### OSHA Classification

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements



**Signal word**

Danger

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 2 / 11  
Version 3

## Hazard statements

H302 - Harmful if swallowed  
H360D - May damage the unborn child

## Precautionary Statements - EU (§28, 1272/2008)

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 CENTER or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

### Other hazards

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

## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## 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 (EU Index 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 classified	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 3 / 11  
Version 3

				[CLP]			
Mannitol (CAS #: 69-65-8)	43	-	200-711-8	Not classified	Not classified	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 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Diltiazem Hydrochloride 33286-22-5	560	271	No data available	No data available	No data available
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## 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

Inhalation	Remove to fresh air. If not breathing, give artificial respiration.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

### 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, CO <sub>2</sub> , alcohol-resistant foam or water spray.
------------------------------	--

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

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 4 / 11  
Version 3

<b>Specific hazards arising from the chemical</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Hazardous combustion products</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	No information available.
<b>Sensitivity to static discharge</b>	No information available.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

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

<b>Personal precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

<b>Environmental precautions</b>	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

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
------------------------------------	--

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

<b>Advice on safe handling</b>	Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

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

<b>Storage Conditions</b>	Store as directed by product packaging.
---------------------------	---

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 5 / 11  
Version 3

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

#### Personal protective equipment

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.

#### Eye/face protection

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.).

#### Hand protection

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.).

#### Skin and body protection

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.).

#### Respiratory protection

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.).

#### Thermal hazards

No information available.

#### Environmental exposure controls

No information available.

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 6 / 11  
Version 3

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Appearance	Lyophilized powder
Physical state	Powder
Color	Off-white
Odor	No information available.
Odor threshold	No information available

#### Property

#### Values

Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

### 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

#### 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 information available.
------------	---------------------------

### 10.2. Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

#### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 10.3. Possibility of hazardous reactions

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 7 / 11  
Version 3

**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**

#### **Short term**

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.

#### **Long Term:**

##### **Known Clinical Effects:**

Animal studies have shown a potential to cause adverse effects on the fetus. Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.

#### **Acute toxicity**

Classification is based on mixture calculation methods based on component data

##### **Serious eye damage/eye irritation**

Based on available data, the classification criteria are not met.

##### **Skin corrosion/irritation**

Based on available data, the classification criteria are not met.

##### **Respiratory or skin sensitization**

Based on available data, the classification criteria are not met.

##### **STOT - single exposure**

Based on available data, the classification criteria are not met.

##### **STOT - repeated exposure**

Based on available data, the classification criteria are not met.

##### **Reproductive toxicity**

Classification is based on mixture calculation methods based on component data.

##### **Germ cell mutagenicity**

Based on available data, the classification criteria are not met.

##### **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 )	= 271 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

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 8 / 11  
Version 3

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

### **11.2.2. Other information**

**Other adverse effects** No information available.

## **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.



# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 9 / 11  
Version 3

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

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.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable

## Section 15: REGULATORY INFORMATION

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

Diltiazem Hydrochloride	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Developmental
<b>EINECS</b>	251-443-3
Mannitol	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 10 / 11  
Version 3

**TSCA**  
**EINECS**  
**AICS**

Present  
200-711-8  
Present

## National regulations

### Germany

#### **Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

### **TRGS 905**

Not applicable

### **Switzerland**

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material**

Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20**

Not applicable

**Major Accidents Ordinance SR 814.012**

Not applicable

### **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 (EU) 2024/590**

Not applicable.

### **Explosives Precursors Marketing and Use (2019/1148)**

Not applicable

### Legend:

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

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

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

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TCSI** - Taiwan Chemical Substance Inventory

### 15.2. Chemical safety assessment

#### **Chemical Safety Report**

No information available

# SAFETY DATA SHEET

Product Name Diltiazem Hydrochloride for Injection (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 11 / 11  
Version 3

## Section 16: OTHER INFORMATION

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

#### **Full text of any hazard and/or precautionary statements referred to under Sections 2-15**

H302 - Harmful if swallowed H360D - May damage the unborn child

**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** 13-Jun-2025

**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.**