



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 07-Nov-2018

Version: 1.1

Page 1 of 8

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

### Product Identifier

**Material Name:** Diltiazem Hydrochloride for Injection (Hospira, Inc.)

**Trade Name:** Not established

**Chemical Family:** Calcium channel blocker

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

### 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

### Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

### Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4

Reproductive Toxicity: Category 1B

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H302 - Harmful if swallowed

H360D - May damage the unborn child

May form combustible dust concentrations in air

## SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride for Injection (Hospira, Inc.)

Revision date: 07-Nov-2018

Page 2 of 8

Version: 1.1

### 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  
P281 - Use personal protective equipment as required  
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  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations



### 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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Diltiazem Hydrochloride	33286-22-5	251-443-3	Acute Tox.4 (H302) Repr.1B (H360D)	57

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	43

### Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

### Description of First Aid Measures

#### Eye Contact:

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

## SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride for Injection (Hospira, Inc.)

Page 3 of 8

Revision date: 07-Nov-2018

Version: 1.1

- Skin Contact:** Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
- Ingestion:** Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.
- Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### Most Important Symptoms and Effects, Both Acute and Delayed

- 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.
- Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

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

### Environmental Precautions

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

### Methods and Material for Containment and Cleaning Up

- 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.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for 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.

## SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride for Injection (Hospira, Inc.)

Page 4 of 8

Revision date: 07-Nov-2018

Version: 1.1

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical active

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

#### Diltiazem Hydrochloride

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

### 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.

**Hands:** 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.)

**Eyes:** 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.)

**Skin:** 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.)

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Lyophilized powder  
**Odor:** No data available.  
**Molecular Formula:** Mixture

**Color:** Off-white  
**Odor Threshold:** No data available.  
**Molecular Weight:** Mixture

**Solvent Solubility:** No data available  
**Water Solubility:** No data available  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.

### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Diltiazem Hydrochloride

No data available

#### Mannitol

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

## SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride for Injection (Hospira, Inc.)

Page 5 of 8

Revision date: 07-Nov-2018

Version: 1.1

Vapor Pressure (kPa): No data available  
Vapor Density (g/ml): No data available  
Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
Flammability (Solids): No data available  
Flash Point (Liquid) (°C): No data available  
Upper Explosive Limits (Liquid) (% by Vol.): No data available  
Lower Explosive Limits (Liquid) (% by Vol.): No data available

## 10. STABILITY AND REACTIVITY

Reactivity: No data available  
Chemical Stability: Stable under normal conditions of use.  
Possibility of Hazardous Reactions  
Oxidizing Properties: No data available  
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  
Hazardous Decomposition Products: No data available

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

**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:** Animal studies have shown a potential to 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.

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

#### Diltiazem Hydrochloride

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

#### Mannitol

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

### 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

## SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride for Injection (Hospira, Inc.)

Page 6 of 8

Revision date: 07-Nov-2018

Version: 1.1

### 11. TOXICOLOGICAL INFORMATION

6 Month(s) Dog Oral 10 mg/kg/day LOEL Heart, Liver, Cardiovascular system  
1 Year(s) Dog Oral 5 mg/kg/day LOEL Cardiovascular system, Heart

#### Reproduction & Developmental Toxicity: (Study Type, 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

#### 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 investigated. Releases to the environment should be avoided.

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride for Injection (Hospira, Inc.)

Page 7 of 8

Revision date: 07-Nov-2018

Version: 1.1

### 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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Diltiazem Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity 2/27/2001
Australia (AICS):	Present
EU EINECS/ELINCS List	251-443-3

#### Mannitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

## SAFETY DATA SHEET

**Material Name:** Diltiazem Hydrochloride for Injection (Hospira, Inc.)

**Page 8 of 8**

**Revision date:** 07-Nov-2018

**Version:** 1.1

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 10 - Stability and Reactivity.

**Revision date:** 07-Nov-2018

Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**