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

**Product Identifier**

<table>
<thead>
<tr>
<th>Material Name:</th>
<th>Diltiazem Hydrochloride Injection (Hospira, Inc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>Not established</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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

- **Intended Use:** Pharmaceutical product used for angina high blood pressure (hypertension)

**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
- Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

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

2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification**

- Reproductive Toxicity: Category 1B

**Label Elements**

- **Signal Word:** Danger
- **Hazard Statements:** H360D - May damage the unborn child

**Precautionary Statements:**

- P202 - Do not handle until all safety precautions have been read and understood
- P281 - Use personal protective equipment as required
- 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
SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride Injection (Hospira, Inc.)
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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) | 0.5 |
| SODIUM HYDROXIDE | 1310-73-2 | 215-185-5 | Skin Corr. 1A (H314) ** | |
| HYDROCHLORIC ACID | 7647-01-0 | 231-595-7 | Skin Corr.1B (H314) STOT SE 3 (H335) ** | |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
| Water for Injection | 7732-18-5 | 231-791-2 | Not Listed | * |
| Sodium citrate, dihydrate | 6132-04-3 | Not Listed | Not Listed | * |
| Citric acid, anhydrous | 77-92-9 | 201-069-1 | Not Listed | * |
| Sorbitol | 6706-59-8 | Not Listed | Not Listed | * |

Additional Information:
* Proprietary
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.

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.

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.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure: No data available
5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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 the spill if it is safe to do so. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.

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

Avoid breathing vapor or mist. 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.

Conditions for Safe Storage, Including any Incompatibilities

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Diltiazem Hydrochloride

Pfizer OEL TWA-8 Hr: 70µg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### SODIUM HYDROXIDE

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACGIH Ceiling Threshold Limit:</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td><strong>OSHA - Final PELs - TWAs:</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Poland OEL - TWA:</strong></td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td><strong>Slovakia OEL - TWA:</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Slovenia OEL - TWA:</strong></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td><strong>Sweden OEL - TWAs:</strong></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

#### HYDROCHLORIC ACID

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACGIH Ceiling Threshold Limit:</strong></td>
<td>2 ppm</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
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<td>Estonia OEL - TWA</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
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<td>Germany (DFG) - MAK</td>
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<td>Greece OEL - TWA</td>
<td>5 ppm</td>
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<td></td>
<td>7 mg/m³</td>
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<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Italy OEL - TWA</td>
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<td></td>
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<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm</td>
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<tr>
<td></td>
<td>3.0 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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: Liquid
- Odor: No data available.
- Molecular Formula: Mixture
- Solvent Solubility: No data available
- Water Solubility: No data available
- pH: No data available
- Color: No data available
- Odor Threshold: No data available
- Molecular Weight: Mixture

Material Name: Diltiazem Hydrochloride Injection (Hospira, Inc.)
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9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Diltiazem Hydrochloride
No data available
Water for Injection
No data available
Citric acid, anhydrous
No data available
Sodium citrate, dihydrate
No data available
SODIUM HYDROXIDE
No data available
HYDROCHLORIC ACID
No data available
Sorbitol
No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
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
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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

PZ03244
11. TOXICOLOGICAL INFORMATION

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

Citric acid, anhydrous
- Rat Oral LD50 3000 mg/kg

HYDROCHLORIC ACID
- Rat Oral LD 50 238-277 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid, anhydrous
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Mild

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

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

HYDROCHLORIC ACID
SAFETY DATA SHEET

Material Name: Diltiazem Hydrochloride Injection (Hospira, Inc.)
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11. TOXICOLOGICAL INFORMATION

Bacterial Mutagenicity (Ames) Salmonella Negative
In Vivo Micronucleus Rat 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

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly 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

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

SODIUM HYDROXIDE
  CERCLA/SARA 313 Emission reporting: Not Listed
  CERCLA/SARA Hazardous Substances and their Reportable Quantities:
    1000 lb
    454 kg
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 5
    Schedule 6
  EU EINECS/ELINCS List: 215-185-5

HYDROCHLORIC ACID
  CERCLA/SARA 313 Emission reporting: 1.0 %
  CERCLA/SARA Hazardous Substances and their Reportable Quantities:
    5000 lb
    2270 kg
  CERCLA/SARA - Section 302 Extremely Hazardous TPQs:
    500 lb
  CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs:
    5000 lb
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  Standard for the Uniform Scheduling for Drugs and Poisons:
    Schedule 5
    Schedule 6
  EU EINECS/ELINCS List: 231-595-7

Water for Injection
  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:
    EU EINECS/ELINCS List: 231-791-2

Sodium citrate, dihydrate
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Australia (AICS): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>EU EINECS/ELINCS List</th>
<th>Not Listed</th>
</tr>
</thead>
</table>

Citric acid, anhydrous

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 201-069-1 |

Sorbitol

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

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
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: New data sheet.

Revision date: 07-Nov-2018


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.

End of Safety Data Sheet