



# SAFETY DATA SHEET

Revision date: 29-Mar-2017

Version: 1.0

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

### Product Identifier

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

**Trade Name:** Not established

**Chemical Family:** Opioid analgesic

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

**Intended Use:** Pharmaceutical product

### 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:**

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

**Emergency telephone number:**

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

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

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 2

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H361 - Suspected of damaging fertility or the unborn child

#### Precautionary Statements:

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

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

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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	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	<1
Verapamil Hydrochloride	152-11-4	205-800-5	Acute Tox. 3, H301 Repr. 2, H361d 2, H401 Chronic 2, H411	/= 0.25
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	*

### 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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**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.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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### 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 and other sulfur-containing compounds.  
**Fire / Explosion Hazards:** Fine particles (such as mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting 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 spill with absorbent material. Clean spill area thoroughly.  
**Additional Consideration for Large Spills:** 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

### 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 product

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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



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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Switzerland OEL -TWAs

2 ppm

3.0 mg/m<sup>3</sup>

#### Vietnam OEL - TWAs

5 mg/m<sup>3</sup>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Sodium chloride

**Pfizer Occupational Exposure** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)  
**Band (OEB):**

#### Verapamil Hydrochloride

**Pfizer Occupational Exposure** OEB 3 (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)  
**Band (OEB):**

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

##### 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:

Solution

#### Color:

Clear, colorless

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

4.9 (4.0-6.5)

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

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

**Sodium chloride**

No data available

**Water for injection**

No data available

**Verapamil Hydrochloride**

Measured Log P 3.79

**HYDROCHLORIC ACID**

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 dusts, mists and vapors) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

**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.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver (based on components)

**Known Clinical Effects:** May cause low blood pressure and dizziness. Occasional, transient changes reported in liver function tests, but no liver damage seen.

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

**Sodium chloride**

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000 mg/kg

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### **11. TOXICOLOGICAL INFORMATION**

#### **Verapamil Hydrochloride**

Rat Oral LD 50 108 mg/kg  
Mouse Oral LD 50 163mg/kg  
Rat Intravenous LD 50 16mg/kg  
Mouse Intravenous LD 50 5795mg/kg  
Rat Subcutaneous LD 50 107mg/kg

#### **HYDROCHLORIC ACID**

Rat Oral LD 50 238-277 mg/kg  
**Ingestion Acute Toxicity** May be harmful if swallowed

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

#### **Sodium chloride**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

#### **Verapamil Hydrochloride**

Skin Irritation Rabbit Mild

**Irritation / Sensitization Comments:** May cause eye irritation.

**Skin Irritation / Sensitization** May cause mild skin irritation.

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### **Verapamil Hydrochloride**

Reproductive & Fertility Rat Oral 55 mg/kg/day NOAEL Fertility  
Embryo / Fetal Development Rat Oral 60 mg/kg/day NOAEL Not Teratogenic  
Embryo / Fetal Development Rat Oral 60 mg/kg/day LOAEL Fetotoxicity  
Embryo / Fetal Development Rabbit Oral 15 mg/kg/day NOAEL Not Teratogenic

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### **Verapamil Hydrochloride**

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

#### **HYDROCHLORIC ACID**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Micronucleus Rat Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Verapamil Hydrochloride**

18 Month(s) Rat Oral 58 mg/kg/day NOAEL Not carcinogenic  
2 Year(s) Rat Oral 120 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.

#### **HYDROCHLORIC ACID**

**IARC:** Group 3 (Not Classifiable)

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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Verapamil Hydrochloride**

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 2.72 mg/L

*Daphnia magna* (Water Flea) LC50 48 Hours 7.04 mg/L

**Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

**Verapamil Hydrochloride**

*Pimephales promelas* (Fathead Minnow) OECD 28 Day(s) NOEC 0.3 mg/L Growth

*Pimephales promelas* (Fathead Minnow) OECD 28 Day(s) NOEC 0.6 mg/L Survival

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**

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

**Verapamil Hydrochloride**

Measured Log P 3.79

**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.

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### 15. REGULATORY INFORMATION

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

##### Sodium chloride

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	231-598-3

##### 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:	Present
EU EINECS/ELINCS List	231-791-2

##### Verapamil Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	205-800-5

##### 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

Additional Information:

U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child  
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects  
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:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** New data sheet.

**Revision date:** 29-Mar-2017

Product Stewardship Hazard Communication

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

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. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**