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

### 1.1. Product identifier

Product Name Verapamil Hydrochloride Injection (Hospira, Inc.)

Product Code(s) PZ03377
Trade Name: Not applicable
Chemical Family: Opioid analgesic

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

Recommended Use Pharmaceutical product

### 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

Reproductive toxicity Category 2

**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 Warnin

Hazard statements H361 - Suspected of damaging fertility or the unborn child

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Precautionary Statements - EU (§28, P201 - Obtain special instructions before use

1272/2008)

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 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	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
		number		(EC) No. 1272/2008 [CLP]	IIIIII (SCL)		
SODIUM CHLORIDE (CAS #: 7647-14-5)	<1	-	231-598-3	Not classified	Not classified	No data available	No data available
Verapamil Hydrochloride (CAS #: 152-11-4)	= 0.25</td <td></td> <td>205-800-5</td> <td>Acute Tox.3 (H301) Repr.2 (H361d) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)</td> <td>Not classified</td> <td>No data available</td> <td>No data available</td>		205-800-5	Acute Tox.3 (H301) Repr.2 (H361d) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	Not classified	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)		Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 ::	No data available	No data available

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					C>=10%		
NonHazardous							
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)
Water (CAS #: 7732-18-5)	*	-	231-791-2	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	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3550	10000	No data available	No data available	No data available
Verapamil Hydrochloride 152-11-4	114	No data available	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration >=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. Seek immediate medical attention/advice.

Eve 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

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Most important symptoms and

<sup>\*</sup> Proprietary

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effects 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 mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

**Explosion data** 

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

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

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

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.

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean Methods for cleaning up

spill area thoroughly.

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

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

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.

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.

# Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

### **Exposure Limits**

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

Verapamil Hydrochloride

Pfizer OEL TWA-8 Hr: 20 µg/m<sup>3</sup>

**SODIUM CHLORIDE** 

Latvia TWA: 5 mg/m³; Russia MAC: 5 mg/m³

+ Hydrochloric Acid

ACGIH OEL (Ceiling) 2 ppm ACGIH TLV Ceiling

 ACGIH TLV
 Ceiling: 2 ppm

 Austria
 TWA-TMW: 5 ppm;

 TWA-TMW: 8 mg/m³;

STEL-KZGW: 10 ppm (8 X 5 min);

STEL-KZGW: 15 mg/m³ (8 X 5 min);

Bulgaria TWA: 5 ppm;

TWA: 8.0 mg/m<sup>3</sup>; STEL: 10 ppm; STEL: 15.0 mg/m<sup>3</sup>;

Czech Republic 8 mg/m<sup>3</sup>

Ceiling: 15 mg/m<sup>3</sup>

Denmark STEL: 5 ppm;

STEL: 8 mg/m³; Estonia TWA: 5 ppm:

Estonia TWA: 5 ppm; TWA: 8 mg/m³;

STEL: 10 ppm; STEL: 15 mg/m³; TWA: 5 ppm;

European Union TWA: 5 ppm;
TWA: 8 mg/m³;

STEL: 10 ppm; STEL: 15 mg/m<sup>3</sup>; STEL: 5 ppm;

STEL: 7.6 mg/m³;
Germany DFG TWA-MAK: 2 ppm; I(2);

TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m<sup>3</sup>; I(2);

> Peak: 4 ppm; Peak: 6 mg/m<sup>3</sup>;

Germany TRGS TWA-AGW; 2 ppm (exposure factor 2);

TWA-AGW; 3 mg/m³ (exposure factor 2);

Finland

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Hungary TWA-AK: 8 mg/m3;

TWA-AK: 5 ppm; STEL-CK: 165 mg/m<sup>3</sup>;

STEL-CK: 10 ppm; Ireland TWA: 8 mg/m<sup>3</sup>;

TWA: 5 ppm; STEL: 10 ppm;

STEL: 15 mg/m<sup>3</sup>; Italy MDLPS TWA: 5 ppm; TWA: 8 mg/m<sup>3</sup>;

STEL: 10 ppm; STEL: 15 mg/m<sup>3</sup>;

Ceiling Limit Value 2 ppm 3.0 mg/m<sup>3</sup>

Latvia TWA: 5 ppm; TWA: 8 mg/m<sup>3</sup>;

STEL: 10 ppm; STEL: 15 mg/m<sup>3</sup>; TWA: 5 ppm;

Netherlands TWA: 8 mg/m<sup>3</sup>; STEL: 10 ppm;

> STEL: 15 mg/m<sup>3</sup>; TWA-NDS: 5 mg/m<sup>3</sup>;

STEL-NDSCh: 10 mg/m3; Romania TWA: 5 ppm;

TWA: 8 mg/m<sup>3</sup>;

STEL: 10 ppm; STEL: 15 mg/m3; MAC: 5 mg/m<sup>3</sup> TWA: 5 ppm; TWA: 8.0 mg/m<sup>3</sup>;

Ceiling: 15 mg/m<sup>3</sup>; TWA-(VLA-ED): 5 ppm; Spain

> TWA-(VLA-ED): 7.6 mg/m<sup>3</sup>; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m3;

TWA-MAK: 2 ppm; Switzerland TWA-MAK: 3 mg/m<sup>3</sup>;

STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m3;

U.S. - OSHA - Final PELs - Ceiling Limits 5 ppm 7 mg/m<sup>3</sup>

**OSHA PEL** Ceiling: 5 ppm Ceiling: 7 mg/m<sup>3</sup>

(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m<sup>3</sup>

United Kingdom TWA: 1 ppm; gas and aerosol mist

> TWA: 2 mg/m3; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m3; gas and aerosol mist

**Pfizer Occupational Exposure Band** (OEB) Statement:

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.

PZ03377

Poland

Russia

Slovakia

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### 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.

# Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance Solution Physical state Solution Liquid

Color Clear, colorless

Odor No information available.
Odor threshold No information available

<u>Property</u> <u>Values</u>

Melting point / freezing pointNo data availableBoiling point or initial boiling point and boiling rangeNo 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

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No data available Autoignition temperature

**Decomposition temperature** 

No data available SADT (°C) 4.9 (4.0-6.5) pH (as aqueous solution) No data available Kinematic viscosity No data available **Dynamic viscosity** No data available Solubility No data available No data available Vapor pressure 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

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

Verapamil Hydrochloride Measured Log P 3.79

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

Stable under normal conditions. Stability

**Explosion data** 

Sensitivity to mechanical impact No information available. Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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

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

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**General Information:** The information included in this section describes the potential hazards of the individual

ingredients

Repeat-dose studies in animals have shown a potential to cause adverse effects on fetus Long Term:

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

**SODIUM CHLORIDE** 

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg Mouse Oral LD 50 4 g/kg Rabbit Dermal LD 50 > 10 g/kg

Verapamil Hydrochloride

Rat Oral LD 50 114 mg/kg Mouse Oral LD 50 163 mg/kg Rat Intravenous LD 50 16 mg/kg Mouse Intravenous LD 50 8 mg/kg Rat Subcutaneous LD 50 107 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SODIUM CHLORIDE	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat)1 h
Verapamil Hydrochloride	= 114 mg/kg (Rat)	-	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

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

SODIUM CHLORIDE

Skin irritation Rabbit Mild Eye irritation Rabbit Mild

Verapamil Hydrochloride Skin irritation Rabbit Mild

+ Hydrochloric Acid

Skin irritation Severe Eye irritation Severe

**Irritation / Sensitization Comments:** 

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

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

Verapamil Hydrochloride

30 Day(s) Dog Intramuscular 2 mg/kg/day LOAEL Liver

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4 Week(s) Dog Intravenous 0.4 mg/kg/day NOAEL Liver

15-16 Week(s) Dog Oral 12.5 mg/kg/day NOAEL None identified

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

Verapamil Hydrochloride

Reproductive & Fertility Rat Oral 55 mg/kg/day NOAEL Fertility

Embryo / Fetal Development Rat Oral 55 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

Chromosome Aberration Human Lymphocytes Negative In Vivo Sister Chromatid Exchange Hamster 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 102.5 mg/kg/day NOAEL Not carcinogenic

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

OSHA.

+ Hydrochloric Acid

IARC Group 3

### 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:** Releases to the environment should be avoided. See Aquatic toxicity data of the active

ingredient, below:.

12.1. 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 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

### 12.2. Persistence and degradability

No information available. Persistence and degradability

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### 12.3. Bioaccumulative potential

**Bioaccumulation** 

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

Verapamil Hydrochloride Measured Log P 3.79

12.4. Mobility in soil

Mobility in soil No information available.

# 12.5. Results of PBT and vPvB assessment

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

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

### 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.

UN number:
UN proper shipping name:
Not applicable
Not applicable
Packing group:
Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

# Section 15: REGULATORY INFORMATION

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

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CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS 231-791-2 AICS Present

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 231-598-3
AICS Present

Verapamil Hydrochloride

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
EINECS 205-800-5

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus % 1.0 % **Hazardous Substances RQs** 5000 lb **California Proposition 65** Not Listed **TSCA** Present **EINECS** 231-595-7 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Schedule 6

**National regulations** 

Chemical name	French RG number
SODIUM CHLORIDE	RG 78
7647-14-5	

#### <u>Germany</u>

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

**Switzerland** 

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018
Storage of Hazardous Material
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20
Major Accidents Ordinance SR 814.012
Not applicable
Not applicable

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### **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)

Chemical name		Restricted substance per REACH	Substance subject to authorization per
		Annex XVII	REACH Annex XIV
	+ Hydrochloric Acid	75	-
	7647-01-0		1

### **Persistent Organic Pollutants**

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid	25	250
7647-01-0		

# Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE	Plant protection agent
7647-14-5	

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
SODIUM CHLORIDE	Product-type 1: Human hygiene
7647-14-5	
+ Hydrochloric Acid	Product-type 2: Disinfectants and algaecides not intended
7647-01-0	for direct application to humans or animals

# 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

# 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

H361d - Suspected of damaging the unborn child H301 - Toxic if swallowed H401 - Toxic to aquatic life H411 - Toxic to aquatic life with long lasting effects H314 - Causes severe skin burns and eye damage H331 - Toxic if inhaled

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on

Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Added Pfizer OEL (Section 8). Updated Section 11 - Toxicology Information. Updated Section 12 -

Ecological Information. Updated Section 16 - Other Information.

Revision date 18-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.