



SAFETY DATA SHEET

Revision date 30-May-2022

Version 2

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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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

2.2. Label elements

Signal word Warning

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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2.3. Other hazards

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 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	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
SODIUM CHLORIDE (CAS #: 7647-14-5)	<1	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Verapamil Hydrochloride (CAS #: 152-11-4)	<= 0.25		205-800-5	Acute Tox.3 (H301) Repr.2 (H361d) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	Not Listed	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

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Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
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Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 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	3000	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

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. 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.
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, CO2, alcohol-resistant foam or water spray.

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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.

5.3. Advice for firefighters

Special protective equipment 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.

For emergency responders Use personal protection recommended in Section 8.

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.

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

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

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 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.

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

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Exposure Limits

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

Verapamil Hydrochloride

Pfizer OEL TWA-8 Hr: 20 µg/m³

SODIUM CHLORIDE

Latvia

5 mg/m³

Russia

MAC: 5 mg/m³

+ Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

5 ppm

8 mg/m³

STEL 10 ppm

STEL 15 mg/m³

Bulgaria

STEL: 10 ppm

STEL: 15.0 mg/m³

5 ppm

8.0 mg/m³

Czech Republic

8 mg/m³

Ceiling: 15 mg/m³

Estonia

5 ppm

8 mg/m³

STEL: 10 ppm

STEL: 15 mg/m³

European Union

TWA: 5 ppm

TWA: 8 mg/m³

STEL: 10 ppm

STEL: 15 mg/m³

Finland

STEL: 5 ppm

STEL: 7.6 mg/m³

Germany

2 ppm

3.0 mg/m³

Ceiling / Peak: 4 ppm

Ceiling / Peak: 6 mg/m³

Germany

2 ppm

3 mg/m³

Hungary

8 mg/m³

STEL: 16 mg/m³

Ireland

8 mg/m³

5 ppm

STEL: 10 ppm

STEL: 15 mg/m³

Italy

5 ppm

8 mg/m³

STEL: 10 ppm

STEL: 15 mg/m³

Ceiling Limit Value

2 ppm

3.0 mg/m³

Latvia

5 ppm

8 mg/m³

STEL: 10 ppm

STEL: 15 mg/m³

Netherlands

8 mg/m³

STEL: 15 mg/m³

Poland

STEL: 10 mg/m³

5 mg/m³

Romania

5 ppm

8 mg/m³

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Russia	STEL: 10 ppm
Slovakia	STEL: 15 mg/m ³
	MAC: 5 mg/m ³
	5 ppm
Spain	8.0 mg/m ³
	5 ppm
	7.6 mg/m ³
Switzerland	STEL: 10 ppm
	STEL: 15 mg/m ³
	2 ppm
	3 mg/m ³
	STEL: 4 ppm
U.S. - OSHA - Final PELs - Ceiling Limits	STEL: 6 mg/m ³
	5 ppm
OSHA PEL	7 mg/m ³
	(vacated) Ceiling: 5 ppm
	(vacated) Ceiling: 7 mg/m ³
	Ceiling: 5 ppm
United Kingdom	Ceiling: 7 mg/m ³
	TWA: 1 ppm
	TWA: 2 mg/m ³
	STEL: 5 ppm
	STEL: 8 mg/m ³

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.

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.

Environmental exposure controls

No information available.

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

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or international equivalent.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Clear, colorless
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	4.9 (4.0-6.5)
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

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

Verapamil Hydrochloride
Measured Log P 3.79

9.2. Other information

No information available

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

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10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

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

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 fetus (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/m³

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	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Verapamil Hydrochloride	= 114 mg/kg (Rat)	-	-

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+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h
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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:

Eye 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

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

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

+ Hydrochloric Acid

IARC Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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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

Persistence and degradability No information available.

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 No information available.

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 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.

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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: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

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

Water

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 Poisons (SUSMP)	Schedule 5 Schedule 6

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

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:

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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 Annex XVII	Substance subject to authorization per REACH Annex XIV
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

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

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

Legend:

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

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

AICS - Australian Inventory of Chemical Substances

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 H-Statements referred to under section 3

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 Acute toxicity, inhalation-Cat.3; 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.

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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

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is no known information at this time.