



SAFETY DATA SHEET

Revision date 06-Nov-2022

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

1.1. Product identifier

Product Name Vecuronium Bromide for Injection (Hospira Inc)
Product Code(s) PZ03166
Trade Name: Not applicable
Chemical Family: Not determined

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

Recommended Use Pharmaceutical product used for skeletal muscle relaxation

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

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

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.

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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)
Citric acid (CAS #: 77-92-9)	*		201-069-1	Eye Irrit. 2A (H319)SE 3 (H335)	Not Listed	No data available	No data available
Vecuronium bromide (CAS #: 50700-72-6)	1 - 5		256-723-9	Acute Tox. 4 (H302)	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ Phosphoric acid (CAS #: 7664-38-2)	**		231-633-2	Skin Corr. 1B (H314)	Eye Irrit. 2 :: 10%≤C<25% Skin Corr. 1B :: C≥25% Skin Irrit. 2 :: 10%≤C<25%	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)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Mannitol (CAS #: 69-65-8)	*	-	200-711-8	Not classified as hazardous	Not Listed	No data available	No data available
Sodium phosphate, dibasic (CAS #: 7558-79-4)	*		231-448-7	Not classified as hazardous	Not Listed	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	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water	89838.9	No data available	No data available	No data available	No data available

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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
7732-18-5					
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available
Sodium phosphate, dibasic 7558-79-4	17000	No data available	No data available	No data available	No data available
Citric acid 77-92-9	5400	>2000	No data available	No data available	No data available
Vecuronium bromide 50700-72-6	455	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Phosphoric acid 7664-38-2	1530	2740	0.2125	No data available	No data available

Additional information

* Proprietary

** to adjust pH

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.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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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

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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 Avoid use of a filtered vacuum to clean spills of dry solids. Contain the source of the spill or leak. Clean spill area thoroughly. Collect spilled material by a method that controls dust generation.

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

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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 used for. skeletal muscle relaxation.

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.

Vecuronium bromide

Pfizer OEL TWA-8 Hr: 60 µg/m³

Mannitol

Russia

MAC: 10 mg/m³

Sodium phosphate, dibasic

Russia

MAC: 10 mg/m³

Citric acid

Czech Republic

4 mg/m³

Germany

2 mg/m³

Ceiling / Peak: 4 mg/m³

Germany

2 mg/m³

Russia

MAC: 1 mg/m³

Switzerland

2 mg/m³

STEL: 4 mg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

2 mg/m³

STEL 4 mg/m³

Bulgaria

2.0 mg/m³

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³

Estonia

1 mg/m³

STEL: 2 mg/m³

Finland

Ceiling: 2 mg/m³

France

2 mg/m³

Hungary

1 mg/m³

STEL: 2 mg/m³

Ireland

STEL: 2 mg/m³

Ceiling Limit Value

2 mg/m³

Latvia

0.5 mg/m³

Poland

STEL: 1 mg/m³

0.5 mg/m³

Romania

1 mg/m³

STEL: 3 mg/m³

Slovakia

2 mg/m³

Spain

STEL: 2 mg/m³

Switzerland

2 mg/m³

STEL: 2 mg/m³

OSHA PEL

2 mg/m³

(vacated) Ceiling: 2 mg/m³

United Kingdom

STEL: 2 mg/m³

+ Phosphoric acid

ACGIH TLV

STEL: 3 mg/m³

1 mg/m³

Austria

1 mg/m³

STEL 2 mg/m³

Bulgaria

STEL: 2.0 mg/m³

1.0 mg/m³

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

1 mg/m³

Estonia

1 mg/m³

STEL: 2 mg/m³

European Union

TWA: 1 mg/m³

STEL: 2 mg/m³

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Finland	1 mg/m ³ STEL: 2 mg/m ³
France	1 mg/m ³
Germany	2 mg/m ³ Ceiling / Peak: 4 mg/m ³
Germany	2 mg/m ³
Hungary	1 mg/m ³ STEL: 2 mg/m ³
Ireland	1 mg/m ³ STEL: 2 mg/m ³
Italy	1 mg/m ³ STEL: 2 mg/m ³
Latvia	1 mg/m ³ STEL: 2 mg/m ³
Netherlands	1 mg/m ³ STEL: 2 mg/m ³
Poland	STEL: 2 mg/m ³ STEL: 2 mg/m ³
Romania	1 mg/m ³ STEL: 2 mg/m ³
Slovakia	1 mg/m ³
Spain	1 mg/m ³ STEL: 2 mg/m ³
Switzerland	2 mg/m ³ STEL: 4 mg/m ³
OSHA PEL	1 mg/m ³ (vacated) TWA: 1 mg/m ³ (vacated) STEL: 3 mg/m ³
United Kingdom	TWA: 1 mg/m ³ STEL: 2 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

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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.)

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	Powder
Color	White to off-white
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture
Property	Values
pH	No data available
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

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

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Section 10: STABILITY AND REACTIVITY

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

Short term

Active ingredient may be harmful if swallowed.

Long Term:

Repeated or prolonged exposure may cause effects similar to those seen in clinical use.

Known Clinical Effects:

Drugs of this class may cause muscle weakness, respiratory depression.

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)

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

Citric acid

Mouse Oral LD50 5400 mg/kg

Vecuronium bromide

Rat Oral LD50 455 mg/kg

Mouse Oral LD 50 41 mg/kg

Rat Intravenous LD 50 0.20 mg/kg

Mouse Intravenous LD 50 0.05 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

+ Phosphoric acid

Rat Oral LD50 1530 mg/kg

Rabbit Dermal LD 50 2730 mg/kg

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Mannitol	= 13500 mg/kg (Rat)	-	-
Sodium phosphate, dibasic	= 17 g/kg (Rat)	-	-
Citric acid	= 3 g/kg (Rat)	> 2000 mg/kg (Rat)	-
Vecuronium bromide	= 455 mg/kg (Rat)	-	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Phosphoric acid	= 1530 mg/kg (Rat)	= 2740 mg/kg (Rabbit)	> 850 mg/m ³ (Rat) 1 h

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

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

+ Phosphoric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Carcinogenicity

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

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

Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

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

+ Phosphoric acid

Gambusia affinis (Mosquitofish) LC50 96 hours 3-3.5 mg/L

Daphnia magna (Water Flea) EC-50 12 4.6 mg/L

12.2. Persistence and degradability

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Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

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 phosphate, dibasic	PBT assessment does not apply
Citric acid	The substance is not PBT / vPvB
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Phosphoric 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.

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

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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

Mannitol

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-711-8
AICS	Present

Sodium phosphate, dibasic

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-448-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

Citric acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	201-069-1
AICS	Present

Vecuronium bromide

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	256-723-9
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

+ Phosphoric acid

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-633-2
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

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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 Annex XVII	Substance subject to authorization per REACH Annex XIV
Citric acid - 77-92-9	Use restricted. See item 75.	
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Phosphoric acid - 7664-38-2	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

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

Not applicable

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation 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.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. 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 is no known information at this time.