

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

1.1. Product identifier

Product Name Antivenin (Micrurus fulvius), North American Coral Snake Antivenin

Product Code(s) PZ01592 Synonyms CSAV

Trade Name: Antivenin (Micrurus fulvius), North American Coral Snake Antivenin

Item Code H000200637,H000401149

Chemical Family: Not determined

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

Pfizer Inc Pfizer Ireland Pharmaceuticals

66 Hudson Boulevard East OSG Building

New York, New York 10001 Ringaskiddy, Co. Cork.

1-800-879-3477 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

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

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 Not classified

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

2.3. Other hazards

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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.

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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 (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Serum for Coral Snake Antivenin (CAS #: NOT ASSIGNED)	*		Not Listed	Not classified	Not classified	No data available	No data available
PHENOL (CAS #: 108-95-2)	0.25		203-632-7	Acute Tox. 3 (H301) STOT RE 2 (H373) Muta. 2 (H341) Skin Corr.1B (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 1%<=C<3% Skin Corr. 1B :: C>=3% Skin Irrit. 2 :: 1%<=C<3%	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
PHENOL	340	630	No data available	No data available	No data available
108-95-2					

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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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.

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

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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.

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

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Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions**

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 the spill or leak. Collect spilled material by a method that controls dust Methods for cleaning up

generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated

surface thoroughly.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

See section 8 for more information. See section 13 for more information. Reference to other sections

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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

Store as directed by product packaging. **Storage Conditions**

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug 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.

PHENOL

ACGIH 250 mg/g creatinine - urine (Phenol with hydrolysis) - end of shift ACGIH - Skin Absorbers

Skin - potential significant contribution to overall exposure by the

cutaneous route

ACGIH TLV TWA: 5 ppm

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pSk TWA-TMW: 2 ppm; Austria TWA-TMW: 8 mg/m³; STEL-KZGW: 4 ppm (4 X 15 min); STEL-KZGW: 16 mg/m3 (4 X 15 min); Sk Bulgaria TWA: 2 ppm; TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³; Sk Czech Republic 7.5 mg/m³ Ceiling: 15 mg/m³ D* Denmark TWA: 1 ppm; TWA: 4 mg/m³; STEL: 16 mg/m³; STEL: 4 ppm; pSk Estonia TWA: 2 ppm; TWA: 8 mg/m³; STEL: 16 mg/m³; STEL: 4 ppm; Sk **European Union** TWA: 2 ppm; TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m3; pSk Finland 1.3 mmol/L (urine - Total phenol after the shift) Finland TWA: 2 ppm; TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³; pSk France 7.8 mg/m³ Germany DFG Sk **Germany TRGS** TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 8 mg/m³ (exposure factor 2); Germany DFG 120 mg/g Creatinine (urine - Phenol (after hydrolysis) end of exposure or shift) 200 mg/L - BLW (end of exposure or end of shift) urine Hungary TWA-AK: 2 ppm; TWA-AK: 8 mg/m³; STEL-CK: 4 ppm; STEL-CK: 16 mg/m³; pSk Ireland TWA: 2 ppm; TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³; pSk Italy MDLPS TWA: 2 ppm; TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³;

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pSk TWA: 2 ppm; Latvia TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³; pSk Netherlands TWA: 2 ppm; TWA: 8 mg/m³; Sk Poland TWA-NDS: 7.8 mg/m³; STEL-NDSCh: 16 mg/m3; Sk Romania TWA: 2 ppm; TWA: 8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³; Russia TWA: 0.3 mg/m³ MAC: 1 mg/m³ Skin TWA: 2 ppm; Slovakia TWA: 8 mg/m³; Ceiling: 16 mg/m3; pSk Spain 120 mg/g Creatinine Spain TWA-(VLA-ED): 2 ppm; TWA-(VLA-ED): 8 mg/m³; STEL (VLA-EC): 4 ppm; STEL (VLA-EC): 16 mg/m3; pSk Switzerland TWA-MAK: 5 ppm; aerosol, vapour TWA-MAK: 19 mg/m3; aerosol, vapour STEL-KZGW: 5 ppm; aerosol, vapour STEL-KZGW: 19 mg/m3; aerosol, vapour Sk OSHA - Final PELs - Skin Notations: prevent or reduce skin absorption **OSHA PEL** TWA: 5 ppm TWA: 19 mg/m³ (vacated) TWA: 5 ppm (vacated) TWA: 19 mg/m³ dSk Sdv TWA: 2 ppm; United Kingdom TWA: 7.8 mg/m³; STEL: 4 ppm; STEL: 16 mg/m³; pSk

Pfizer Occupational Exposure Band The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake **(OEB) Statement:** (ADI) range, based on available hazard data with appropriate safety factors applied.

Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be

used to achieve exposure control to the bottom of the band.

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8.2. Exposure controls

Personal protective equipment

Engineering controls Engineering controls should be used as the primary means to control exposures. Use

process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all large

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scale operations should be fully enclosed. Air recirculation is not recommended.

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.

Wear safety glasses as minimum protection (goggles recommended). (Eye protection must Eye/face protection

meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double Hand protection

recommended). (Protective gloves must meet the standards in accordance with EN374,

ASTM F1001 or international equivalent.).

Wear impervious disposable protective clothing to prevent skin contact. (Protective clothing Skin and body protection

must meet the standards in accordance with EN13982, ANSI 103 or international

equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure

Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.). Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (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 Lyophilized powder

Physical state Powder

Color No information available No information available. Odor **Odor threshold** No information available

Values

Property Melting point / freezing point No data available

Boiling point or initial boiling point and boiling range No data available No data available

Flammability (solid, gas)

Lower and upper explosion limit/flammability limit

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Lower explosion limit
Upper explosion limit
No data available
No data available
No data available
Autoignition temperature
No data available

Decomposition temperature

SADT (°C) No data available No data available Ha pH (as aqueous solution) No data available Kinematic viscosity No data available **Dynamic viscosity** No data available Solubility No data available Vapor pressure No data available Density and/or relative density No data available

Density and/or relative densityNo data availableBulk densityNo data availableLiquid DensityNo data availableVapor densityNo data available

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

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

Stability Stable under normal conditions.

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

Conditions to avoid Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep

away from heat sources and electrostatic discharge.

10.5. Incompatible materials

Incompatible materialsAs 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: Toxicological properties of the formulation have not been fully investigated. The information

included in this section describes the potential hazards of the individual ingredients

Short term May cause skin irritation. May be harmful if absorbed through the skin. (based on

components)

Known Clinical Effects: Individuals sensitive to this material or other materials in its chemical class may develop

allergic reactions. Serious allergic reactions, including anaphylaxis, have been reported. Based on human experience, possible adverse effects following exposure to this compound may include flushing, itching, hives, redness and swelling of the skin (urticaria), shortness of

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breath (dyspnea), blue appearance (cyanosis) and vomiting.

Acute toxicity Based on available data, the cl

Serious eye damage/eye irritation Based

Skin corrosion/irritation

Respiratory or skin sensitization STOT - single exposure STOT - repeated exposure Reproductive toxicity Germ cell mutagenicity

Carcinogenicity
Aspiration hazard

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

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

PHENOL

Rat Oral LD50 317 mg/kg Rat Dermal LD50 525 mg/kg Rabbit Dermal LD50 630 mg/kg Mouse Oral LD50 270 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
PHENOL	= 340 mg/kg (Rat)	= 630 mg/kg (Rabbit)	-

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

2 Generation Reproductive Toxicity Rat Oral 1000 ppm NOAEL No effects at maximum dose Embryo / Fetal Development Rat Oral 120 mg/kg LOAEL Fetotoxicity, Not Teratogenic Fertility and Embryonic Development Rat Oral 53 mg/kg LOAEL Maternal Toxicity, Fetotoxicity, Not Teratogenic

Embryo / Fetal Development Rat Intraperitoneal 200 mg/kg NOAEL No effects at maximum dose

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

103 Week(s) Rat Oral 5,000 ppm NOAEL Not carcinogenic 103 Week(s) Mouse Oral 5,000 ppm NOAEL Not carcinogenic

CarcinogenicityNone of the components of this formulation are listed as a carcinogen by IARC, NTP or

OSHA.

PHENOL

IARC Group 3

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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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: Environmental properties of the formulation have not been investigated. Releases to the

environment should be avoided.

12.1. Toxicity

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

PHENOL

Selenastrum capricornutum (Green Alga) EC50 96 hours 150 mg/L Pimephales promelas (Fathead Minnow) LC50 96 24 mg/L Oncorhynchus mykiss (Rainbow Trout) LC50 96 hours 8.9 mg/L Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 23.88 mg/L Daphnia magna (Water Flea) LC50 48 hours 13 mg/L

12.2. Persistence and degradability

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

Chemical name	PBT and vPvB assessment	
PHENOL	Not PBT/vPvB	

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

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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.

Chemical name	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
PHENOL	-	-	-	U188

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is not regulated for transportation / carriage.

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

Section 15: REGULATORY INFORMATION

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

Serum for Coral Snake Antivenin

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed

PHENOL

CERCLA/SARA Section 313 de minimus % 1.0 % **Hazardous Substances RQs** 1000 lb Not Listed California Proposition 65 **TSCA** Present 203-632-7 **EINECS** Present **AICS** Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Schedule 6 Schedule 2

Schedule 4

National regulations

<u>National regulations</u>				
Chemical name	French RG number			
PHENOL	RG 14			

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Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

Chemical name	Number	Class
PHENOL	5.2.5	Class I
108-95-2		

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Not applicable Not applicable WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Major Accidents Ordinance SR 814.012

Not applicable Not applicable

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)

		(* 1 = 1 + 1 + 1), * 1 1 1 1 1 1 1 1 1		
Chemical name		Restricted substance per REACH	Substance subject to authorization per	
		Annex XVII	REACH Annex XIV	
	PHENOL	75	-	
	108-95-2			

Persistent Organic Pollutants

Not applicable

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

Not applicable.

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

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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

H314 - Causes severe skin burns and eye damage H301 - Toxic if swallowed H341 - Suspected of causing genetic defects H331 - Toxic if inhaled H373 - May cause damage to organs through prolonged or repeated exposure

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

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

Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

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Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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