SAFETY DATA SHEET

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
66 Hudson Boulevard East
New York, New York 10001
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

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.

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)
Serum for Coral Snake Antivenin (CAS #: NOT ASSIGNED)	*		Not Listed	Not classified as hazardous	Not Listed	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	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
PHENOL 108-95-2	340	630	No data available	No data available	No data available

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 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.

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
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

Storage Conditions Store as directed by product packaging.

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
ACGIH - Skin Absorbers	Skin - potential significant contribution to overall exposure by the cutaneous route
ACGIH TLV	5 ppm S*
Austria	2 ppm 8 mg/m³ STEL 4 ppm STEL 16 mg/m³ H*
Bulgaria	STEL: 4 ppm STEL: 16 mg/m³ 2 ppm 8 mg/m³ K*
Czech Republic	7.5 mg/m³ Ceiling: 15 mg/m³ D*
Denmark	1 ppm 4 mg/m³ H*
Estonia	2 ppm 8 mg/m³ STEL: 16 mg/m³ STEL: 4 ppm A*
European Union	TWA: 2 ppm TWA: 8 mg/m³ STEL: 4 ppm

	STEL: 16 mg/m³ *
Finland	1.3 mmol/L
Finland	2 ppm 8 mg/m³ STEL: 4 ppm STEL: 16 mg/m³ iho*
France	7.8 mg/m³
Germany	Skin
Germany	2 ppm 8 mg/m³ H*
Germany	120 mg/g Creatinine
Hungary	8 mg/m³ STEL: 16 mg/m³ b*
Ireland	2 ppm 8 mg/m³ STEL: 4 ppm STEL: 16 mg/m³ Sk*
Italy	2 ppm 8.0 mg/m³ STEL: 4 ppm STEL: 16 mg/m³ pelle*
Latvia	2 ppm 8 mg/m³ STEL: 4 ppm STEL: 16 mg/m³ *
Netherlands	8 mg/m³ H*
Poland	STEL: 16 mg/m³ 7.8 mg/m³
Romania	2 ppm 8 mg/m³ STEL: 4 ppm STEL: 16 mg/m³ P*
Russia	TWA: 0.3 mg/m³ MAC: 1 mg/m³ Skin
Slovakia	2 ppm 8 mg/m³ K*
Spain	120 mg/g Creatinine
Spain	2 ppm 8 mg/m³ STEL: 4 ppm STEL: 16 mg/m³ vía dérmica*
Switzerland	5 ppm 19 mg/m³ STEL: 5 ppm STEL: 19 mg/m³ H*
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption

OSHA PEL	5 ppm 19 mg/m^3 (vacated) TWA: 5 ppm (vacated) TWA: 19 mg/m^3 (vacated) S* S*
United Kingdom	TWA: 2 ppm TWA: 7.8 mg/m^3 STEL: 4 ppm STEL: 16 mg/m^3 Sk*

Pfizer Occupational Exposure Band (OEB) Statement: The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (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.

8.2. Exposure controls

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

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 as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

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

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	Lyophilized powder
Color	No information available
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

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

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

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)

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

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

PHENOL

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

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	The substance is not PBT / vPvB

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.

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

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
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

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
California Proposition 65 Not Listed
TSCA Present
EINECS 203-632-7
AICS Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) Schedule 5
Schedule 6
Schedule 2
Schedule 4

Chemical name	French RG number	Title

PHENOL 108-95-2	RG 14	-

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
PHENOL - 108-95-2	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

Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled Specific target organ toxicity, repeated exposure-Cat.2; 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. Updated Section 12 - Ecological Information.

Revision date 26-Mar-2023

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.