MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

Trade Name:	Antivenin (Micrurus fulvius), North American Coral Snake Antivenin
Synonyms:	CSAV
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Powder, freeze-dried

Statement of Hazard: The workplace and environmental characteristics of this substance have not been fully evaluated. Exposure by any route or releases to the environment should be avoided.

Additional Hazard Information:
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.

EU Classification
EU Indication of danger: Not classified
(Bad file name or number)

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ammonium sulfate	7783-20-2	231-984-1	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C;R35	<1.0
Serum for Coral Snake Antivenin	Not Assigned	Not Listed	Not Listed	###
Acetic acid	64-19-7	200-580-7	C;R35 R10	<1.0
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Phenol	108-95-2	203-632-7	C;R34 T;R24/25	<1.0

Additional Information: * Proprietary
as required Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	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. Restrict access to work area. 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.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ammonium sulfate

Bulgaria OEL - TWA	10.0 mg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3

Acetic acid

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia STEL	15 ppm 37 mg/m^3
Australia TWA	10 ppm 25 mg/m^3
Austria OEL - MAKs	10 ppm 25 mg/m^3
Belgium OEL - TWA	10 ppm 25 mg/m^3
Bulgaria OEL - TWA	25.0 mg/m^3
Cyprus OEL - TWA	10 ppm 25 mg/m^3
Czech Republic OEL - TWA	25 mg/m^3
Denmark OEL - TWA	10 ppm 25 mg/m^3
Estonia OEL - TWA	10 ppm 25 mg/m^3
Finland OEL - TWA	5 ppm 13 mg/m^3
Germany - TRGS 900 - TWAs	10 ppm 25 mg/m^3
Germany (DFG) - MAK	10 ppm 25 mg/m^3
Greece OEL - TWA	10 ppm 25 mg/m^3
Hungary OEL - TWA	25 mg/m^3
Ireland OEL - TWAs	10 ppm 25 mg/m^3
Latvia OEL - TWA	10 ppm 25 mg/m^3
Lithuania OEL - TWA	10 ppm 25 mg/m^3
Luxembourg OEL - TWA	10 ppm 25 mg/m^3
Malta OEL - TWA	10 ppm 25 mg/m^3
OSHA - Final PELS - TWAs:	10 ppm 25 mg/m^3
Poland OEL - TWA	15 mg/m^3
Portugal OEL - TWA	10 ppm
Romania OEL - TWA	10 ppm 25 mg/m^3
Slovakia OEL - TWA	10 ppm 25 mg/m^3
Slovenia OEL - TWA	10 ppm 25 mg/m^3
Spain OEL - TWA	10 ppm 25 mg/m^3
Sweden OEL - TWAs	5 ppm 13 mg/m^3

Sodium chloride

Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Phenol

ACGIH Threshold Limit Value (TWA)	5 ppm
ACGIH - Biological Exposure Limit:	250 mg/g creatinine
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	1 ppm 4 mg/m^3
Austria OEL - MAKs	2 ppm 8 mg/m^3
Belgium OEL - TWA	2 ppm 8 mg/m^3
Bulgaria OEL - TWA	7.8 mg/m^3
Bulgaria - Biological Exposure Limit:	200 mg/L
Cyprus OEL - TWA	8 mg/m^3 2 ppm
Czech Republic OEL - TWA	7.5 mg/m^3
Denmark OEL - TWA	1 ppm 4 mg/m^3
Estonia OEL - TWA	2 ppm 8 mg/m^3
Finland OEL - TWA	2 ppm 8 mg/m^3
Finland - Biological Exposure Limit:	1.3 mmol/L
France OEL - TWA	2 ppm 7.8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 8 mg/m^3
Germany - Biological Exposure Limit:	300 mg/L
Greece OEL - TWA	2 ppm 8 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	2 ppm 8 mg/m^3
Italy OEL - TWA	2 ppm 7.8 mg/m^3
Latvia OEL - TWA	2 ppm 8 mg/m^3
Lithuania OEL - TWA	2 ppm 8 mg/m^3
Luxembourg OEL - TWA	2 ppm 8 mg/m^3
Malta OEL - TWA	2 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
OSHA - Final PELS - TWAs:	5 ppm 19 mg/m^3
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption
Poland OEL - TWA	7.8 mg/m^3
Portugal OEL - TWA	5 ppm
Romania OEL - TWA	2 ppm 8 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	2 ppm 7.8 mg/m^3
Slovak Republic - Biological Exposure Limit:	200 mg/L
Slovenia OEL - TWA	2 ppm 7.8 mg/m^3
Spain OEL - TWA	2 ppm 8 mg/m^3
Spain - Biological Exposure Limit:	250 mg/g Creatinine
Sweden OEL - TWAs	1 ppm 4 mg/m^3

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.

Serum for Coral Snake Antivenin

Pfizer Occupational Exposure Band (OEB): B-OEB Default (control exposure to the range of 10 µg/day to <100 µg/day)

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: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear impervious, disposable gloves as minimum protection (double recommended).

Eyes: Wear safety glasses as minimum protection.

Skin: Wear impervious disposable protective clothing when handling this compound. Full body protection recommended (scale dependent).

Respiratory protection: If airborne exposures are within or exceed the Biotherapeutic Occupational Exposure Band (B-OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the B-OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder	**Color:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

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.

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

Phenol
Rat Oral LD50 317 mg/kg
Rat Dermal LD50 669 mg/kg
Rat Inhalation LC50 316 mg/m^3

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Acetic acid
Rat Oral LD50 3530 mg/kg
Mouse Inhalation LC50 5000 ppm

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

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

Phenol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Phenol
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

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

Acetic acid
Pimephales promelas (Fathead Minnow) LC-50 1 Hours > 315 mg/L
Pimephales promelas (Fathead Minnow) LC-50 24 Hours 122 mg/L
Mysidopsis bahia (Mysid Shrimp) LC-50 48 Hours 100-300 mg/L

12. ECOLOGICAL INFORMATION

13. DISPOSAL CONSIDERATIONS

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 waste water 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.

Phenol

RCRA - U Series Wastes	Listed

14. TRANSPORT INFORMATION

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

This material is not regulated for transportation / carriage.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
The workplace and environmental characteristics of this substance have not been fully evaluated. Exposure by any route or releases to the environment should be avoided.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
(Bad file name or number)

Ammonium sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-984-1

Sodium hydroxide

15. REGULATORY INFORMATION

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Acetic acid

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Phenol

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb 10000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	203-632-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R10 - Flammable.
R34 - Causes burns.
R35 - Causes severe burns.
R24/25 - Toxic in contact with skin and if swallowed.

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

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

End of Safety Data Sheet