



SAFETY DATA SHEET

Revision date: 09-Sep-2016

Version: 5.0

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

Product Identifier

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

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning
Hazard Statements: May form combustible dust concentrations in air

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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Serum for Coral Snake Antivenin	Not Assigned	Not Listed	Not Listed	*
PHENOL	108-95-2	203-632-7	Acute Tox. 3 (H301) STOT RE 2 (H373) Muta. 2 (H341) Skin Corr.1B (H314) Acute Tox. 3 (H331)	0.25

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

PHENOL

ACGIH Threshold Limit Value (TWA)	5 ppm
ACGIH - Biological Exposure Limit:	250 mg/g creatinine
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	2 ppm
	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
	7.8 mg/m ³

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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:	120 mg/g
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 8.0 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
Poland OEL - TWA	7.8 mg/m ³
Portugal OEL - TWA	2 ppm 8 mg/m ³
Romania OEL - TWA	2 ppm 8 mg/m ³
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 8 mg/m ³
Spain OEL - TWA	2 ppm 8 mg/m ³
Spain - Biological Exposure Limit:	120 mg/g Creatinine
Sweden OEL - TWAs	1 ppm 4 mg/m ³
Switzerland OEL - TWAs	5 ppm 19 mg/m ³
Vietnam OEL - TWAs	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)

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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.
- 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.
- Hands:** 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.)
- Eyes:** 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.)
- Skin:** 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 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | | |
|---------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Lyophilized powder | Color: | No data available. |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |
- Solvent Solubility:** No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Serum for Coral Snake Antivenin
No data available
PHENOL
No data available
Decomposition Temperature (°C): No data available.
- Evaporation Rate (Gram/s):** No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
- Flammability:**
- | | |
|---|-------------------|
| Autoignition Temperature (Solid) (°C): | No data available |
| Flammability (Solids): | No data available |
| Flash Point (Liquid) (°C): | No data available |

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Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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: (Species, Route, End Point, Dose)

PHENOL

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

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

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

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11. TOXICOLOGICAL INFORMATION

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.

Toxicity:

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

PHENOL

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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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.

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15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Serum for Coral Snake Antivenin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

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
California Proposition 65	Not Listed
EU EINECS/ELINCS List	203-632-7

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in 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.
Reasons for Revision:	Updated Section 11 - Toxicology Information. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	09-Sep-2016 Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet