



# MATERIAL SAFETY DATA SHEET

Revision date: 21-Aug-2006

Version: 1.2

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

**Pfizer Inc**  
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**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-262-8200

**Emergency telephone number:**  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Thrombin (topical)

**Trade Name:** Thrombostat®  
**Chemical Family:** Not determined  
**Intended Use:** blood clotting agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Hydrogen chloride	7647-01-0	231-595-7	<1
Sodium chloride	7647-14-5	231-598-3	~0.5M
Sodium hydroxide	1310-73-2	215-185-5	<1
Calcium chloride USP	10035-04-8	Not listed	~0.15M
Prothrombin from bovine plasma (US origin)	9001-26-7	232-592-3	*
Purified lung extract from bovine lungs (US origin)	NOT ASSIGNED	Not listed	*

Ingredient	CAS Number	EU EINECS List	%
Glycine	56-40-6	200-272-2	1.5

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Sterile, freeze-dried powder plus sterile diluent  
**Signal Word:** CAUTION

**Statement of Hazard:** Can cause allergic reaction Pharmaceutical blood clotting agent: may be fatal if injected or enters bloodstream

**Eye Contact:** Dust may cause irritation.

**Skin Contact:** May cause allergic skin reaction. See 'Known clinical effects', below.

**Inhalation:** See 'Known clinical effects', below.

**Ingestion:** See 'Known clinical effects', below.

**Known Clinical Effects:** This product contains protein of bovine origin. Those with known sensitivity should avoid contact. Serious allergic reactions, including anaphylaxis, have been reported.

**Potential Health Effects:** Extensive intravascular clotting and death may result if injected or allowed to enter large blood vessels.

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**EU Indication of danger:** Irritant

**EU Hazard Symbols:**

R43 - May cause sensitization by skin contact.

**Additional Information:  
Note:**

For a more detailed discussion of potential health hazards and toxicity see Section 11. 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.

### 4. FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Keep patient at rest. Get medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** As for primary cause of fire.

**Hazardous Combustion Products:** Not known

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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

**Additional Information:** This material is not expected to support combustion.

### 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 the spill or leak. Wipe up with a damp cloth and place in container for disposal. 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:** Vacuum or sweep material into appropriate recovery container. Close container and move it to a secure holding area.

**Additional Information:** Review Sections 3, 8 and 12 before proceeding with clean up.

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### 7. HANDLING AND STORAGE

**General Handling:** Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist. Use only in a well-ventilated area.

**Storage Conditions:** Store under refrigeration in closed container.

**Storage Temperature:** 15 - 25°C (50 - 77°F)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hydrogen chloride**  
ACGIH Ceiling Threshold Limit: 2 ppm

**Sodium hydroxide**  
OSHA - Final PELs - TWAs: 2 mg/m<sup>3</sup>  
ACGIH Ceiling Threshold Limit: 2 mg/m<sup>3</sup>

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

**Personal Protective Equipment:**

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** This product contains protein of bovine origin. Those with known sensitivity should avoid contact. Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the skin.

**Respiratory protection:** None required under normal conditions of use. Use dust mask for dusty conditions.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

**Physical State:** Freeze-dried Powder in vial  
**Molecular Formula:** Mixture  
**Color:** White to off-white  
**Molecular Weight:** Mixture

**Solubility:** Soluble: Isotonic solutions

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** No data available  
**Incompatible Materials:** No data available

**Hazardous Decomposition Products:** None expected under normal conditions.  
**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The primary hazard identified in clinical use is sensitization. This product contains protein of bovine origin. Those with known sensitivity should avoid contact. Extensive intravascular clotting and death may result if injected or allowed to enter large blood vessels.

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

### Calcium chloride USP

Rat Oral LD50 1000 mg/kg  
Mouse Oral LD50 1940 mg/kg

### Sodium chloride

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD 50 4 g/kg

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

### Hydrogen chloride

Rat Inhalation LC50 1H 3,124 ppm  
Mouse Inhalation LC50 1H 1,108 ppm  
Mouse Oral LD50 900 mg/kg

**Inhalation Acute Toxicity** No data available

**Ingestion Acute Toxicity** See table for data on a minor component.

### Sodium chloride

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

### Eye Irritation / Sensitization

Dust may cause irritation.

### Skin Irritation / Sensitization

Thrombin is an antigenic substance of bovine origin and has caused sensitivity and allergic reactions including anaphylaxis. Not a significant irritant in clinical use

### Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

**Subchronic Effects** No data available

### Teratogenicity

No data available

### Mutagenicity

No data available

### Carcinogen Status:

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

### Hydrogen chloride

#### IARC:

Group 3

### At increase risk from exposure:

Individuals with a known hypersensitivity to any of its component and/or to material of bovine origin.

## 12. ECOLOGICAL INFORMATION

### Environmental Overview:

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Symbol:** Xi  
**EU Indication of danger:** Irritant

**EU Risk Phrases:** R43 - May cause sensitization by skin contact.

**EU Safety Phrases:** S24 - Avoid contact with skin.

**OSHA Label:**  
CAUTION  
Can cause allergic reaction Pharmaceutical blood clotting agent: may be fatal if injected or enters bloodstream

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

### Glycine

EU EINECS List	200-272-2
Inventory - United States TSCA - Sect. 8(b)	Listed

### Hydrogen chloride

CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb TPQ
EU EINECS List	5000 lb
Inventory - United States TSCA - Sect. 8(b)	231-595-7
	Listed

### Sodium chloride

EU EINECS List	231-598-3
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Inventory - United States TSCA - Sect. 8(b)                      Listed

**Sodium hydroxide**

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ
EU EINECS List	454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	215-185-5
	Listed

**Prothrombin from bovine plasma (US origin)**

EU EINECS List	232-592-3
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### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**