



# SAFETY DATA SHEET

Revision date: 08-Sep-2017

Version: 1.1

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

### Product Identifier

**Material Name:** Thrombi-Gel (Thrombin/gelatin hemostat)

**Trade Name:** THROMBI-GEL

**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product used as topical wound dressing

### 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

Skin Sensitization: Category 1

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H317 - May cause an allergic skin reaction

**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing must not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)  
P363 - Wash contaminated clothing before reuse  
P501 - Dispose of contents/container in accordance with all local and national regulations

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### 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.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Calcium chloride USP	10035-04-8	Not Listed	Eye Irrit. 2 (H319)	<10
Formaldehyde	50-00-0	Not Listed	Carc.2 (H351) Acute Tox.3 (H331) Acute Tox.3 (H311) Acute Tox.3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317)	<0.1
Thrombin	9002-04-4	232-648-7	Skin Sens. 1; H317	2

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	*

#### 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.

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.

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**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** No data available

**Exposure:**

**Medical Conditions** None known

**Aggravated by Exposure:**

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

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

**Products:**

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

### Advice for Fire-Fighters

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

## 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 /** Contain the source of spill if it is safe to do so. Collect spilled material by a method that  
**Collecting:** controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for** Non-essential personnel should be evacuated from affected area. Report emergency  
**Large Spills:** situations immediately. Cleanup operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Restrict access to work area. Avoid contact with eyes, skin and clothing. Avoid breathing dust, vapor or mist. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

### Conditions for Safe Storage, Including any Incompatibilities

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

**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	dermal sensitizer respiratory sensitizer
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	0.5 ppm
	0.6 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Finland OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
France OEL - TWA	0.5 ppm
Germany - TRGS 900 - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.3 ppm
	0.37 mg/m <sup>3</sup> no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm
	2.5 mg/m <sup>3</sup>
Hungary OEL - TWA	0.6 mg/m <sup>3</sup>
Ireland OEL - TWAs	2 ppm
	2.5 mg/m <sup>3</sup>
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.5 ppm
	0.6 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.15 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	2 ppm
	0.5 ppm
	0.75 ppm
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Romania OEL - TWA	1 ppm
	1.20 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.3 ppm
	0.37 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.5 ppm
	0.62 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.3 ppm
	0.37 mg/m <sup>3</sup>
Vietnam OEL - TWAs	0.5 mg/m <sup>3</sup>

#### Calcium chloride USP

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**Pfizer Occupational Exposure Band (OEB):** OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

#### Thrombin

**Pfizer Occupational Exposure Band (OEB):** B-OEB 5 (control exposure to <10 µg/day)

#### Exposure Controls

**Engineering Controls:** Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels within the OEB range.

**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:** 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.)

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

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

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solid	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**

**Carboxymethylcellulose sodium**

No data available

**Formaldehyde**

No data available

**Gelatin**

No data available

**Thrombin**

No data available

**Calcium chloride USP**

No data available

**Decomposition Temperature (°C):** No data available.

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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  
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 dust and mists) may fuel fires/explosions.  
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:** The information included in this section describes the potential hazards of the individual ingredients.  
**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. Extensive intravascular clotting and death may result if injected or allowed to enter large blood vessels.

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

#### Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg  
Rat Oral LD50 27,000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### Formaldehyde

Rat Oral LD50 100 mg/kg  
Rat Inhalation LC50/4h 0.48mg/L  
Mouse Inhalation LC50/4h 0.414mg/L  
Rabbit Dermal LD50 270mg/kg

#### Thrombin

Rat Subcutaneous LD50 > 40 mg/kg  
Rat IP LD50 > 40mg/kg  
Mouse Subcutaneous LD50 > 50mg/kg

#### Calcium chloride USP

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

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

##### Formaldehyde

Skin Irritation Rabbit Severe  
Eye Irritation Rabbit Severe  
Skin Sensitization - Beuhler Guinea Pig Positive  
Skin Sensitization - GPMT Guinea Pig Positive

##### Calcium chloride USP

Eye Irritation Rabbit Moderate

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

##### Formaldehyde

90 Day(s) Rat Inhalation 1.6 ppm NOAEL Lungs  
13 Week(s) Rat Inhalation 0.0012 mg/L NOAEL Lungs, Respiratory system  
4 Week(s) Rat Oral 25 mg/kg NOAEL Gastrointestinal system  
13 Week(s) Mouse Inhalation 0.002 mg/L NOAEL Lungs, Respiratory system

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

##### Formaldehyde

Embryo / Fetal Development Rat Inhalation 40 ppm NOAEL Not Teratogenic, Maternal Toxicity  
Embryo / Fetal Development Mouse Oral 185 mg/kg NOAEL Not Teratogenic, Maternal Toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive  
*In Vitro* Chromosome Aberration Rat Positive  
*In Vitro* Sister Chromatid Exchange Rat Positive  
*In Vivo* Chromosome Aberration Rat Positive

##### Thrombin

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors  
2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

#### Carcinogen Status:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen. See below

##### Formaldehyde

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### 11. TOXICOLOGICAL INFORMATION

IARC: Group 1 (Carcinogenic to Humans)  
NTP: Known Human Carcinogen  
OSHA: Listed

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated.

**Toxicity:**

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

**Formaldehyde**

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	EPA	LC50	96 Hours	118 ppm
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	24 Hours	42 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.

**Formaldehyde**

RCRA - U Series Wastes

Listed

### 14. TRANSPORT INFORMATION

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

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

### 15. REGULATORY INFORMATION

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



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**15. REGULATORY INFORMATION**

**Calcium chloride USP**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

**Formaldehyde**

CERCLA/SARA 313 Emission reporting	0.1 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb
	45.4 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	100 lb
California Proposition 65	carcinogen 1/1/1988 gas
OSHA - Specifically Regulated Chemicals	2 ppm
	0.5 ppm
	0.75 ppm
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
	Schedule 6
EU EINECS/ELINCS List	Not Listed

**Carboxymethylcellulose sodium**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

**Gelatin**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6

**Thrombin**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-648-7

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### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, dermal-Cat.3; H311 - Toxic in contact with skin  
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled  
Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer  
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 08-Sep-2017  
Product Stewardship Hazard Communication

**Prepared by:** 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**