SAFETY DATA SHEET

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

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

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

EU Classification:

EU Indication of danger: Xi - Irritant

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

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 should 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

Other Hazards No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	GHS Classification	%
Formaldehyde	50-00-0	200-001-8	T; R23/24/25 C; R34 Carc.Cat.3; R40 R43	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	Xi;R43	Skin Sens. 1; H317	2

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Calcium chloride USP	10035-04-8	Not Listed	Not Listed	Eye Irrit. 2 (H319)	*
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	Not Listed	*
Gelatin	9000-70-8	232-554-6	Not Listed	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 R phrases and 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: No data available

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 dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting 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 / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that 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 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

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

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	Sensitizer
Australia STEL	2 ppm 2.5 mg/m^3
Australia TWA	1 ppm 1.2 mg/m^3
Austria OEL - MAKs	0.5 ppm 0.6 mg/m^3
Bulgaria OEL - TWA	1.0 mg/m^3
Czech Republic OEL - TWA	0.5 mg/m^3
Estonia OEL - TWA	0.5 ppm 0.6 mg/m^3
Finland OEL - TWA	0.3 ppm 0.37 mg/m^3
France OEL - TWA	0.5 ppm
Germany (DFG) - MAK	0.3 ppm 0.37 mg/m^3 no irritation should occur during mixed exposure
Greece OEL - TWA	2 ppm 2.5 mg/m^3
Hungary OEL - TWA	0.6 mg/m^3
Ireland OEL - TWAs	2 ppm 2.5 mg/m^3
Japan - OELs - Ceilings	0.2 ppm 0.24 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
Lithuania OEL - TWA	0.5 ppm 0.6 mg/m^3
Netherlands OEL - TWA	0.15 mg/m^3
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^3
Romania OEL - TWA	1 ppm 1.20 mg/m^3
Slovakia OEL - TWA	0.3 ppm 0.37 mg/m^3
Slovenia OEL - TWA	0.5 ppm 0.62 mg/m^3
Sweden OEL - TWAs	0.3 ppm 0.37 mg/m^3
Switzerland OEL -TWAs	0.3 ppm 0.37 mg/m^3
Vietnam OEL - TWAs	0.5 mg/m^3

Thrombin

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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).
Hands:	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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:	Solid	**Color:**	White
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)

Carboxymethylcellulose sodium
No data available

Calcium chloride USP
No data available

Formaldehyde
No data available

Gelatin
No data available

Thrombin
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

Flammablity:

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

Calcium chloride USP
Rat Oral LD50 1000 mg/kg
Mouse Oral LD50 1940mg/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

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

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

11. TOXICOLOGICAL INFORMATION

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

Formaldehyde
90 Day(s) Rat Inhalation1.6 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
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
Oncorhynchus mykiss (Rainbow Trout) EPA LC50 96 Hours 118 ppm
Daphnia magna (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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, and Subdivision B.

Calcium chloride USP

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

15. REGULATORY INFORMATION

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 initial date 1/1/88 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	200-001-8

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

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

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

16. OTHER INFORMATION

Text of R phrases and 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

T - Toxic
C - Corrosive
Carcinogenic: Category 3
Xi - Irritant

R34 - Causes burns.
R40 - Limited evidence of a carcinogenic effect
R43 - May cause sensitization by skin contact.
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Revision date:	22-Nov-2014 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