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

Contact E-Mail: pfizer-MSDS@pfizer.com

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
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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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 Exposure:
- 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 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 / 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. 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

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

**Formaldehyde**

<table>
<thead>
<tr>
<th>Source</th>
<th>Limit</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold Limit</td>
<td>0.3 ppm</td>
<td></td>
</tr>
<tr>
<td>ACGIH - Sensitizer Designation</td>
<td>dermal sensitizer respiratory sensitizer</td>
<td></td>
</tr>
<tr>
<td>Australia STEL</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 ppm</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.3 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>0.3 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>0.3 ppm</td>
<td>0.37 mg/m³ no irritation should occur during mixed exposure</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>0.6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.5 mg/m³</td>
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</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>0.2 ppm</td>
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</tr>
<tr>
<td></td>
<td>0.24 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.15 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>0.75 ppm</td>
<td></td>
</tr>
<tr>
<td>OSHA - Specifically Regulated Chemicals</td>
<td>2 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.75 ppm</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>1 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.20 mg/m³</td>
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</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>0.3 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.62 mg/m³</td>
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</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>0.3 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>0.3 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.37 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**Calcium chloride USP**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Pfizer Occupational Exposure Band (OEB):**

**Thrombin**

OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

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

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

**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

**Formaldehyde**

No data available

**Gelatin**

No data available

**Thrombin**

No data available

**Calcium chloride USP**

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
  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
11. TOXICOLOGICAL INFORMATION

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, NOAEL, 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
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
Onchorhynchus 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
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
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs
  - 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs
- 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
- 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
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

Prepared by: Product Stewardship Hazard Communication

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