



# SAFETY DATA SHEET

Revision date 10-Jan-2023

Version 2

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Thrombi-Gel (Thrombin/gelatin hemostat)  
**Product Code(s)** 00232496  
**Trade Name:** THROMBI-GEL  
**Chemical Family:** Not determined

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as topical wound dressing

### 1.3. Details of the supplier of the safety data sheet

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

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Skin corrosion/irritation** Category 3 - (H316)  
**Respiratory sensitization** Category 1 - (H334)  
**Skin sensitization** Category 1 - (H317)

### 2.2. Label elements

**Signal word** Danger

**Hazard statements**  
H316 - Causes mild skin irritation  
H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

**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

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P501 - Dispose of contents/container in accordance with all local and national regulations



## 2.3. Other hazards

### 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 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.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Calcium chloride USP (CAS #: 10035-04-8)	<10		Not Listed	Eye Irrit 2A (H319)	Not Listed	No data available	No data available
Thrombin (CAS #: 9002-04-4)	2		232-648-7	Eye Irrit.2 (H319) Skin Irrit.2 (H315) Skin Sens.1 (H317) Resp.Sens.1 (H334) STOT SE.3 (H335)	Not Listed	No data available	No data available
+ Formaldehyde (CAS #: 50-00-0)	<0.1		200-001-8	Acute Tox. 3 (H301) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Carc. 2 (H351) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 5%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 5%<=C<25% Skin Sens. 1 :: C>=0.2% STOT SE 3 ::	No data available	No data available

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					C>=5%		
NonHazardous							
Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Gelatin (CAS #: 9000-70-8)	*		232-554-6	Not classified as hazardous	Not Listed	No data available	No data available
Carboxymethylcellulose sodium (CAS #: 9004-32-4)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

## Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Carboxymethylcellulose sodium 9004-32-4	27000	No data available	No data available	No data available	No data available
Calcium chloride USP 10035-04-8	1000	No data available	No data available	No data available	No data available
+ Formaldehyde 50-00-0	100	2000	No data available	No data available	463

## Additional information

+ Substance with a Union workplace exposure limit

\* Proprietary

Non-hazardous ingredients provided for completeness. 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and** For information on potential signs and symptoms of exposure, See Section 2 - Hazards

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**effects** Identification and/or Section 11 - Toxicological Information.

## **4.3. Indication of any immediate medical attention and special treatment needed**

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### **5.1. Extinguishing media**

**Suitable Extinguishing Media** Dry chemical, CO<sub>2</sub>, alcohol-resistant foam or water spray.

### **5.2. Special hazards arising from the substance or mixture**

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

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

### **5.3. Advice for firefighters**

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### **6.1. Personal precautions, protective equipment and emergency procedures**

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

**For emergency responders** Use personal protection recommended in Section 8.

### **6.2. Environmental precautions**

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

### **6.3. Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### **6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

#### **Advice on 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

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## 7.2. Conditions for safe storage, including any incompatibilities

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

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

#### Gelatin

Russia MAC: 10 mg/m<sup>3</sup>

#### Carboxymethylcellulose sodium

Russia MAC: 10 mg/m<sup>3</sup>

#### + Formaldehyde

ACGIH TLV STEL: 0.3 ppm  
0.1 ppm

Austria 0.3 ppm  
0.37 mg/m<sup>3</sup>  
STEL 0.6 ppm  
STEL 0.74 mg/m<sup>3</sup>

Bulgaria STEL: 0.5 ppm  
STEL: 0.74 mg/m<sup>3</sup>  
STEL: 0.6 ppm  
0.37 mg/m<sup>3</sup>  
0.3 ppm

Czech Republic 0.62 mg/m<sup>3</sup>  
0.37 mg/m<sup>3</sup>  
Ceiling: 0.74 mg/m<sup>3</sup>  
D\*

Denmark Ceiling: 0.28 ppm  
Ceiling: 0.437 mg/m<sup>3</sup>

Estonia 0.5 ppm  
0.6 mg/m<sup>3</sup>  
STEL: 1 ppm

European Union STEL: 1.2 mg/m<sup>3</sup>  
TWA: 0.37 mg/m<sup>3</sup>  
TWA: 0.3 ppm

Finland \*  
0.3 ppm  
0.37 mg/m<sup>3</sup>  
STEL: 0.6 ppm  
STEL: 0.74 mg/m<sup>3</sup>

France 0.37 mg/m<sup>3</sup>  
0.62 mg/m<sup>3</sup>

Germany 0.3 ppm no irritation should occur during mixed exposure  
0.37 mg/m<sup>3</sup> no irritation should occur during mixed exposure  
Ceiling / Peak: 0.6 ppm  
Ceiling / Peak: 0.74 mg/m<sup>3</sup>

Germany 0.3 ppm  
0.37 mg/m<sup>3</sup>

Hungary 0.37 mg/m<sup>3</sup>  
STEL: 0.74 mg/m<sup>3</sup>  
b\*

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Ireland	0.3 ppm 0.5 ppm 0.37 mg/m <sup>3</sup> 0.62 mg/m <sup>3</sup> STEL: 0.6 ppm STEL: 0.738 mg/m <sup>3</sup> STEL: 0.62 mg/m <sup>3</sup>
Italy	0.37 mg/m <sup>3</sup> 0.3 ppm 0.62 mg/m <sup>3</sup> 0.5 ppm STEL: 0.74 mg/m <sup>3</sup> STEL: 0.6 mg/m <sup>3</sup> pelle*
Ceiling Limit Value	0.2 ppm 0.24 mg/m <sup>3</sup>
Latvia	0.37 mg/m <sup>3</sup> 0.62 mg/m <sup>3</sup> 0.3 ppm 0.5 ppm STEL: 0.74 mg/m <sup>3</sup> STEL: 0.6 ppm
Netherlands	0.15 mg/m <sup>3</sup> STEL: 0.5 mg/m <sup>3</sup>
Poland	STEL: 0.74 mg/m <sup>3</sup>
Romania	0.37 mg/m <sup>3</sup> 1 ppm 1.2 mg/m <sup>3</sup> STEL: 2 ppm STEL: 3 mg/m <sup>3</sup> MAC: 0.5 mg/m <sup>3</sup>
Russia	Skin
Slovakia	0.3 ppm 0.37 mg/m <sup>3</sup>
Spain	0.3 ppm 0.37 mg/m <sup>3</sup> STEL: 0.6 ppm STEL: 0.74 mg/m <sup>3</sup>
Switzerland	0.3 ppm 0.37 mg/m <sup>3</sup> STEL: 0.6 ppm STEL: 0.74 mg/m <sup>3</sup>
OSHA PEL	0.75 ppm (vacated) TWA: 3 ppm unless specified in 1910.1048 (vacated) STEL: 10 ppm 30 min unless specified in 1910.1048 (vacated) Ceiling: 5 ppm unless specified in 1910.1048 STEL: 2 ppm see 29 CFR 1910.1048
United Kingdom	TWA: 2 ppm TWA: 2.5 mg/m <sup>3</sup> STEL: 2 ppm STEL: 2.5 mg/m <sup>3</sup>

**Pfizer Occupational Exposure Band (OEB) Statement:** The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

## Calcium chloride USP

Pfizer Occupational Exposure OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>,

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Band (OEB): provide additional precautions to protect from skin contact)

## Thrombin

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

Band (OEB):

## 8.2. 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. All operations should be fully enclosed. No air recirculation permitted.

### Environmental exposure controls

No information available.

### Personal protective equipment

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. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

### Eye/face protection

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

### Hand protection

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.).

### Skin and body protection

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.).

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Physical state

solid

#### Color

White

#### Odor

No information available.

#### Odor threshold

No information available

#### Molecular formula

Mixture

#### Molecular weight

Mixture

#### Property

#### Values

#### pH

No data available

#### Melting point / freezing point

No data available

#### Boiling point / boiling range

#### Flash point

No information available

#### Evaporation rate

No data available

#### Flammability (solid, gas)

No data available

#### Flammability Limit in Air

#### Upper flammability limit:

No data available

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<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	No data available
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## 9.2. Other information

No information available

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

**Reactivity** No data available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

### 10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**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



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vessels.  
**Acute toxicity** Based on available data, the classification criteria are not met.  
**Serious eye damage/eye irritation** Based on available data, the classification criteria are not met.  
**Skin corrosion/irritation** Classification is based on mixture calculation methods based on component data.  
**Respiratory or skin sensitization** Classification is based on mixture calculation methods based on component data.  
**STOT - single exposure** Based on available data, the classification criteria are not met.  
**STOT - repeated exposure** Based on available data, the classification criteria are not met.  
**Reproductive toxicity** Based on available data, the classification criteria are not met.  
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.  
**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Aspiration hazard** Based on available data, the classification criteria are not met.

## 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 2301 mg/kg  
Mouse Oral LD50 1940 mg/kg  
Rabbit Dermal LD50 > 5000 mg/kg

### Thrombin

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

### + Formaldehyde

Rat Oral LD50 800 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Carboxymethylcellulose sodium	= 27000 mg/kg ( Rat )	-	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
+ Formaldehyde	= 100 mg/kg ( Rat )	> 2000 mg/kg ( Rat )	< 463 ppm ( Rat ) 4 h

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

### Calcium chloride USP

Eye Irritation Rabbit Moderate

### + Formaldehyde

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate Severe

## 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) Dog Inhalation Not Specified Lungs  
90 Day(s) Rat Inhalation Not Specified Lungs  
90 Day(s) Monkey Inhalation Not Specified Lungs  
9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

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

### + Formaldehyde

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

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

### Thrombin

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

## **+ Formaldehyde**

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive

*In Vitro* Chromosome Aberration Rodent Positive

*In Vitro* Sister Chromatid Exchange Rodent Positive

*In Vivo* Chromosome Aberration Not specified Positive

## **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

**Carcinogenicity** 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

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

### **11.2.2. Other information**

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** Releases to the environment should be avoided. Environmental properties of the formulation have not been investigated.

### **12.1. Toxicity**

**No information available**

### **12.2. Persistence and degradability**

**Persistence and degradability** No information available.

### **12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

### **12.4. Mobility in soil**

**Mobility in soil** No information available.

### **12.5. Results of PBT and vPvB assessment**

**PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
+ Formaldehyde	The substance is not PBT / vPvB PBT assessment does not apply

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## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 wastewater 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.

Chemical name	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
+ Formaldehyde	-	-	-	Present

## Section 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.

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable  
  
**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Gelatin		
<b>CERCLA/SARA Section 313 de minimus %</b>		Not Listed
<b>California Proposition 65</b>		Not Listed
<b>TSCA</b>		Present
<b>EINECS</b>		232-554-6
<b>AICS</b>		Present
Carboxymethylcellulose sodium		
<b>CERCLA/SARA Section 313 de minimus %</b>		Not Listed
<b>California Proposition 65</b>		Not Listed
<b>TSCA</b>		Present
<b>EINECS</b>		Not Listed
<b>AICS</b>		Present
Calcium chloride USP		

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<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present
Thrombin	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	232-648-7
<b>AICS</b>	Present
+ Formaldehyde	
<b>CERCLA/SARA Section 313 de minimus %</b>	0.1 %
<b>Hazardous Substances RQs</b>	100 lb
<b>California Proposition 65</b>	carcinogen 1/1/1988 gas
<b>TSCA</b>	Present
<b>EINECS</b>	200-001-8
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 6 Schedule 2

## France

### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Gelatin 9000-70-8	RG 88	-
+ Formaldehyde 50-00-0	RG 43	-

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
+ Formaldehyde - 50-00-0	Use restricted. See item 72. Use restricted. See item 28. Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Formaldehyde - 50-00-0	5	50

## EU - Biocides

Chemical name	EU - Biocides
+ Formaldehyde - 50-00-0	Product-type 22: Embalming and taxidermist fluids

### Legend: \_\_\_\_\_

# SAFETY DATA SHEET

Product Name Thrombi-Gel (Thrombin/gelatin hemostat)  
Revision date 10-Jan-2023

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**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under 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. Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation. Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation.

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

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date** 10-Jan-2023

**Prepared By** Pfizer Global Environment, Health, and Safety

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