



## MATERIAL SAFETY DATA SHEET

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### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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**KING PHARMACEUTICALS, INC.**  
**501 Fifth Street**  
**Bristol, TN 37620**

**EMERGENCY TELEPHONE**  
**NUMBER: 1-800-776-3637**  
**TECHNICAL ASSISTANCE:**  
**1-800-776-3637**

**SUBSTANCE: Thrombi-Gel® (thrombin/gelatin hemostat)**

**TRADE NAMES/SYNONYMS:**

Thrombi-Gel 10 - Product Number 60793-907-01 (reference number 0907); Thrombi-Gel 40 - Product Number 60793-908-04 (reference number 0908); Thrombi-Gel 100 - Product Number 60793-909-10 (reference number 0909); 00232496

**PRODUCT DESCRIPTION:** Each Thrombi-Gel consists of bovine derived thrombin, sodium carboxymethylcellulose, and calcium chloride, lyophilized within an elastic gelatin sponge. Read package insert prior to use.

**CREATION DATE:** Mar 12 2007

**REVISION DATE:** Mar 28 2007

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### 2. COMPOSITION, INFORMATION ON INGREDIENTS

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**COMPONENT: TYPE A, PORCINE GELATIN**

**CAS NUMBER:** 9000-70-8

**PERCENTAGE:** 76-82.5

**COMPONENT: SODIUM CARBOXYMETHYL CELLULOSE**

**CAS NUMBER:** 9004-32-4

**PERCENTAGE:** 10-13

**COMPONENT: CALCIUM CHLORIDE, DIHYDRATE**

**CAS NUMBER:** 10035-04-8

**PERCENTAGE:** 7-9

**COMPONENT: TOPICAL BOVINE THROMBIN, USP**

**CAS NUMBER:** 9002-04-4

**PERCENTAGE:** 0.5-2

**COMPONENT:** FORMALDEHYDE  
**CAS NUMBER:** 50-00-0  
**PERCENTAGE:** not more than 0.2 mg/sponge

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### 3. HAZARDS IDENTIFICATION

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**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=1 REACTIVITY=0



#### **EMERGENCY OVERVIEW:**

**COLOR:** white

**PHYSICAL FORM:** sponge

**MAJOR HEALTH HAZARDS:** respiratory tract irritation, skin irritation, eye irritation, blood damage, allergic reactions, antibody formation against bovine thrombin may cause adverse hemostatic effects

#### **POTENTIAL HEALTH EFFECTS:**

##### **INHALATION:**

**SHORT TERM EXPOSURE:** irritation, cough, allergic reactions, antibody response, nausea, vomiting, difficulty breathing, headache, blood disorders

**LONG TERM EXPOSURE:** irritation, cough, antibody response, allergic reactions, nosebleed, stomach pain, chest pain, difficulty breathing, wheezing, asthma, headache, lung damage

##### **SKIN CONTACT:**

**SHORT TERM EXPOSURE:** irritation, allergic reactions, antibody response, absorption may occur, itching, nausea, vomiting, headache, blood disorders

**LONG TERM EXPOSURE:** irritation, itching, antibody response, allergic reactions, blood disorders

##### **EYE CONTACT:**

**SHORT TERM EXPOSURE:** irritation, itching, tearing

**LONG TERM EXPOSURE:** irritation

##### **INGESTION:**

**SHORT TERM EXPOSURE:** gastrointestinal irritation, nausea, vomiting, stomach pain, irregular heartbeat, drowsiness, convulsions

**LONG TERM EXPOSURE:** no information on significant adverse effects

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### 4. FIRST AID MEASURES

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**INHALATION:** Not a likely route of exposure. It is unlikely that emergency treatment will be required if used as directed.

**SKIN CONTACT:** This product is intended for topical use. It is unlikely that emergency treatment will be required if used as directed.

**EYE CONTACT:** It is unlikely that emergency treatment will be required if used as directed. If contact does occur, flush eyes with plenty of water for at least 15 minutes and then get medical attention.

**INGESTION:** Not a likely route of exposure. If swallowed, get medical attention.

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### 5. FIRE FIGHTING MEASURES

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**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard.

**EXTINGUISHING MEDIA:** carbon dioxide, regular dry chemical, regular foam, water

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

**HAZARDOUS COMBUSTION PRODUCTS:**

Thermal decomposition products or combustion: oxides of carbon, oxides of sodium, oxides of calcium, hydrogen chloride

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## 6. ACCIDENTAL RELEASE MEASURES

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**WATER RELEASE:**

Subject to California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Keep out of water supplies and sewers.

**OCCUPATIONAL RELEASE:**

Move undamaged containers from spill area. Small dry spills: Sweep and scoop spilled material into clean, dedicated equipment. Keep out of water supplies and sewers. Notify Local Emergency Planning Committee and State Emergency Response Commission for release greater than or equal to RQ (U.S. SARA Section 304). If release occurs in the U.S. and is reportable under CERCLA Section 103, notify the National Response Center at (800)424-8802 (USA) or (202)426-2675 (USA).

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## 7. HANDLING AND STORAGE

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**STORAGE:** Store and handle in accordance with all current regulations and standards. Store between 2 C and 25 C. See original container for storage recommendations. Keep separated from incompatible substances.

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## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

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**EXPOSURE LIMITS:**

**Thrombi-Gel® (thrombin/gelatin hemostat):**

No occupational exposure limits established.

**VENTILATION:** Under normal conditions of use, no special ventilation equipment is needed.

**EYE PROTECTION:** Eye protection not required under normal conditions.

**CLOTHING:** Wear appropriate clothing to minimize skin contact.

**GLOVES:** Wear appropriate chemical resistant gloves.

**RESPIRATOR:** No respirator is required under normal conditions of use.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

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**PHYSICAL STATE:** solid  
**APPEARANCE:** foil wrapped  
**COLOR:** white  
**PHYSICAL FORM:** sponge  
**ODOR:** Not available  
**BOILING POINT:** Not applicable  
**MELTING POINT:** Not available  
**VAPOR PRESSURE:** Not applicable  
**VAPOR DENSITY:** Not applicable  
**SPECIFIC GRAVITY:** Not available  
**WATER SOLUBILITY:** Not available  
**PH:** Not applicable  
**VOLATILITY:** Not applicable  
**ODOR THRESHOLD:** Not available  
**EVAPORATION RATE:** Not applicable  
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available

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## 10. STABILITY AND REACTIVITY

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**REACTIVITY:** Stable at normal temperatures and pressure.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

**INCOMPATIBILITIES:** oxidizing materials

**HAZARDOUS DECOMPOSITION:**

Thermal decomposition products or combustion: oxides of carbon, oxides of sodium, oxides of calcium, hydrogen chloride

**POLYMERIZATION:** Will not polymerize.

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## 11. TOXICOLOGICAL INFORMATION

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**Thrombi-Gel® (thrombin/gelatin hemostat):**

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** blood system disorders, known sensitivity to bovine-derived products, known sensitivity to porcine-derived products, allergic reactions  
**ADDITIONAL DATA:** Individuals who are known to be sensitive to bovine-derived substances should not be exposed to this material. Individuals who are known to be sensitive to porcine-derived substances should not be exposed to this material. Refer to the current package insert for additional information.

**GELATIN:**

**LOCAL EFFECTS:**

Irritant: inhalation, eye

**REPRODUCTIVE EFFECTS DATA:** Available.

**SODIUM CARBOXYMETHYL CELLULOSE:**

**TOXICITY DATA:** >5800 mg/m<sup>3</sup>/4 hour(s) inhalation-rat LC50; >2 gm/kg skin-rabbit LD50; 27000 mg/kg oral-rat LD50

**ACUTE TOXICITY LEVEL:**

Relatively Non-toxic: ingestion

**TUMORIGENIC DATA:** Available.

**REPRODUCTIVE EFFECTS DATA:** Available.

**CALCIUM CHLORIDE, DIHYDRATE:**

**TOXICITY DATA:** >5000 mg/kg skin-rabbit LD50

**LOCAL EFFECTS:**

Irritant: inhalation, skin, eye

**MUTAGENIC DATA:** Available.

**BOVINE THROMBIN:**

**TOXICITY DATA:** >3 gm/kg skin-mouse LD50

**LOCAL EFFECTS:**

Irritant: inhalation, skin, eye

**TARGET ORGANS:** blood

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** blood system disorders, known sensitivity to bovine-derived products

**MUTAGENIC DATA:** Available.

**ADDITIONAL DATA:** For topical use only. Not for intravenous administration. This substance may be fatal if it enters the bloodstream. Individuals who are known to be sensitive to bovine-derived substances should not be exposed to this material.

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## 12. ECOLOGICAL INFORMATION

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**ENVIRONMENTAL SUMMARY:** Highly toxic to aquatic life.

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## 13. DISPOSAL CONSIDERATIONS

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Dispose in accordance with all applicable regulations. Dispose in a puncture-resistant biohazard container.

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## 14. TRANSPORT INFORMATION

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**U.S. DEPARTMENT OF TRANSPORTATION:** No classification assigned.

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## 15. REGULATORY INFORMATION

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**U.S. REGULATIONS:**

**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):**

**Formaldehyde:** 100 LBS RQ

**METHYL ALCOHOL (METHANOL):** 5000 LBS RQ

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):**  
Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):**

Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):**

ACUTE: No

CHRONIC: No

FIRE: No

REACTIVE: No

SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29CFR1910.119):**

**Formaldehyde:** 1000 LBS TQ

**STATE REGULATIONS:**

**California Proposition 65:**

Known to the state of California to cause the following:

**Formaldehyde**

Cancer (Jan 01, 1988)

**NATIONAL INVENTORY STATUS:**

**U.S. INVENTORY (TSCA):** This product is exempt.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

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**16. OTHER INFORMATION**

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