



# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

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

**SUBSTANCE: THROMBIN-JMI®**

### TRADE NAMES/SYNONYMS:

BOVINE THROMBIN, TOPICAL USP; NDC 60793-215-05 (5,000 I.U. per vial with 5 mL diluent); NDC 60793-217-20 (20,000 I.U. per vial with 20 mL diluent); NDC 60793-217-21 (20,000 I.U. per vial with 20 mL diluent, spray pump, and actuator); NDC 60793-217-22 (20,000 I.U. per vial with 20 mL diluent, spray tip, and syringe); NDC 60793-205-05 (5,000 I.U. per vial with 5 mL diluent, nasal drug delivery device); 00230638

**CREATION DATE:** Jul 28 2004

**REVISION DATE:** May 02 2008

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

**COMPONENT:** TOPICAL BOVINE THROMBIN, USP

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

**PERCENTAGE:** 15

**COMPONENT:** MANNITOL

**CAS NUMBER:** 69-65-8

**PERCENTAGE:** <85

**COMPONENT:** SODIUM CHLORIDE

**CAS NUMBER:** 7647-14-5

**PERCENTAGE:** <85

## 3. HAZARDS IDENTIFICATION

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

### EMERGENCY OVERVIEW:

**COLOR:** tan

**PHYSICAL FORM:** powder

**ODOR:** odorless

**MAJOR HEALTH HAZARDS:** eye irritation, blood damage, antibody formation against bovine thrombin



may cause adverse hemostatic effects

**PHYSICAL HAZARDS:** Dust/air mixtures may ignite or explode.

**POTENTIAL HEALTH EFFECTS:**

**INHALATION:**

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

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

**SKIN CONTACT:**

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

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

**EYE CONTACT:**

**SHORT TERM EXPOSURE:** irritation

**LONG TERM EXPOSURE:** irritation

**INGESTION:**

**SHORT TERM EXPOSURE:** gastrointestinal irritation, chills, fever, nausea, vomiting, diarrhea, loss of appetite, chest pain, dizziness, disorientation, lung congestion, effects on the brain, convulsions, coma

**LONG TERM EXPOSURE:** changes in blood pressure, kidney damage

---

## 4. FIRST AID MEASURES

---

**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

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

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If a large amount is swallowed, get medical attention.

---

## 5. FIRE FIGHTING MEASURES

---

**FIRE AND EXPLOSION HAZARDS:** Slight fire hazard. Dust/air mixtures may ignite or explode.

**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. Water or foam may cause frothing.

**HAZARDOUS COMBUSTION PRODUCTS:**

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

---

## 6. ACCIDENTAL RELEASE MEASURES

---

**OCCUPATIONAL RELEASE:**

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers.

---

## 7. HANDLING AND STORAGE

---

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

**HANDLING:** Use methods to minimize dust.

---

## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

---

**EXPOSURE LIMITS:**

**THROMBIN-JMI®:**

No occupational exposure limits established.

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

**EYE PROTECTION:** Wear splash resistant safety goggles. Provide eye wash bottles in the immediate work area.

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

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

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

---

## 9. PHYSICAL AND CHEMICAL PROPERTIES

---

**PHYSICAL STATE:** solid

**APPEARANCE:** light

**COLOR:** tan

**PHYSICAL FORM:** powder

**ODOR:** odorless

**BOILING POINT:** Not applicable

**MELTING POINT:** Not available

**VAPOR PRESSURE:** Not applicable

**VAPOR DENSITY:** Not applicable

**SPECIFIC GRAVITY:** Not available

**WATER SOLUBILITY:** soluble

**PH:** Not applicable

**VOLATILITY:** Not applicable

**ODOR THRESHOLD:** Not available

**EVAPORATION RATE:** Not applicable

**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available

---

## 10. STABILITY AND REACTIVITY

---

**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 or combustion products: oxides of carbon, oxides of sodium, hydrogen chloride

**POLYMERIZATION:** Will not polymerize.

---

## 11. TOXICOLOGICAL INFORMATION

---

**THROMBIN-JMI®:**

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** allergic reactions, blood system disorders

**ADDITIONAL DATA:** Allergic reactions may occur in individuals that are sensitive to bovine materials.

Refer to the current package insert for additional information.

**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.

**MANNITOL:**

**TOXICITY DATA:** 13500 mg/kg oral-rat LD50

**ACUTE TOXICITY LEVEL:**

Slightly Toxic: ingestion

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** heart or respiratory disorders, kidney disorders

**MUTAGENIC DATA:** Available.

**SODIUM CHLORIDE:**

**IRRITATION DATA:** 50 mg/24 hour(s) skin-rabbit mild; 500 mg/24 hour(s) skin-rabbit mild; 100 mg eyes-rabbit mild; 100 mg/24 hour(s) eyes-rabbit moderate; 10 mg eyes-rabbit moderate

**TOXICITY DATA:** >42 gm/m<sup>3</sup>/1 hour(s) inhalation-rat LC50; >10 gm/kg skin-rabbit LD50; 3000 mg/kg oral-rat LD50

**LOCAL EFFECTS:**

Irritant: eye

**ACUTE TOXICITY LEVEL:**

Moderately Toxic: ingestion

**MUTAGENIC DATA:** Available.

**REPRODUCTIVE EFFECTS DATA:** Available.

---

## 12. ECOLOGICAL INFORMATION

---

Not available

---

### 13. DISPOSAL CONSIDERATIONS

---

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

---

### 14. TRANSPORT INFORMATION

---

**U.S. DEPARTMENT OF TRANSPORTATION:** Not regulated.

---

### 15. REGULATORY INFORMATION

---

**U.S. REGULATIONS:**

**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**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):** Not regulated.

**STATE REGULATIONS:**

**California Proposition 65:** Not regulated.

**NATIONAL INVENTORY STATUS:**

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

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

---

### 16. OTHER INFORMATION

---

“RTECS®” is a United States trademark owned and licensed under authority of the U.S. Government, by and through Symyx Technologies, Inc.

©Copyright 1984-2008 Symyx Technologies, Inc. All rights reserved.

While we believe the information provided herein is accurate and current, King Pharmaceuticals, Inc. makes no representations or warranties, either expressed or implied, and assumes no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information.