



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/m³/1 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

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