



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: BICILLIN(R) L-A

TRADE NAMES/SYNONYMS:

3,3-DIMETHYL-7-OXO-6-((PHENYLACETYL)AMINO)-(2S-(2ALPHA, 5ALPHA, 6ALPHA))-4-THIA-1-AZABICYCLO(3.2.0)HEPTANE-2-CARBOXYLIC ACID, TETRAHYDRATE; PENICILLIN G BENZATHINE SUSPENSION; NDC# 60793-700-10 (600,000 units; pediatric); NDC# 60793-701-10 (1.2 mil units; adult); NDC# 60793-702-10 (2.4 mil units; adult); 00230797

CHEMICAL FAMILY: antibiotic/antiseptic

PRODUCT USE: pharmaceutical

CREATION DATE: Nov 15 2004

REVISION DATE: Jan 04 2007

2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: PENICILLIN G BENZATHINE, TETRAHYDRATE

CAS NUMBER: 41372-02-5

PERCENTAGE: 45

COMPONENT: INERT INGREDIENTS

CAS NUMBER: Not assigned.

PERCENTAGE: balance

3. HAZARDS IDENTIFICATION

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

EMERGENCY OVERVIEW:

COLOR: white



PHYSICAL FORM: suspension

ODOR: odorless

MAJOR HEALTH HAZARDS: allergic reactions

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: allergic reactions, asthma

LONG TERM EXPOSURE: no information on significant adverse effects

SKIN CONTACT:

SHORT TERM EXPOSURE: irritation, allergic reactions, asthma

LONG TERM EXPOSURE: same as effects reported in short term exposure

EYE CONTACT:

SHORT TERM EXPOSURE: irritation, allergic reactions

LONG TERM EXPOSURE: no information on significant adverse effects

INGESTION:

SHORT TERM EXPOSURE: allergic reactions

LONG TERM EXPOSURE: rash, nausea, vomiting, diarrhea, stomach pain, chest pain, wheezing, asthma, dizziness, bluish skin color, lung congestion, blood disorders, convulsions

4. FIRST AID MEASURES

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

SKIN CONTACT: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

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.

ANTIDOTE: penicillinase. For anaphylactic reactions, epinephrine; steroids, intravenous.

NOTE TO PHYSICIAN: For inhalation, consider oxygen.

5. FIRE FIGHTING MEASURES

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. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

FLASH POINT: No data available.

HAZARDOUS COMBUSTION PRODUCTS:

Thermal decomposition products or combustion: oxides of carbon, oxides of nitrogen, oxides of sulfur

6. ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry.

7. HANDLING AND STORAGE

STORAGE: Store and handle in accordance with all current regulations and standards. Store in a tightly closed container. Avoid contact with light. Protect from freezing. Store between 2 C and 8 C. Refrigerate. See original container for storage recommendations. Keep separated from incompatible substances.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:**BICILLIN(R) L-A:**

No occupational exposure limits established.

VENTILATION: Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

EYE PROTECTION: Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Wear appropriate chemical resistant clothing.

GLOVES: Wear appropriate chemical resistant gloves.

PROTECTIVE MATERIAL TYPES: rubber

RESPIRATOR: Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use. Any chemical cartridge respirator with organic vapor cartridge(s).

Any chemical cartridge respirator with a full facepiece and organic vapor cartridge(s).

Any air-purifying respirator with a full facepiece and an organic vapor canister.

For Unknown Concentrations or Immediately Dangerous to Life or Health -

Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full facepiece.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: liquid

APPEARANCE: opaque

COLOR: white

TEXTURE: viscous

PHYSICAL FORM: suspension

ODOR: odorless

BOILING POINT: Not available

FREEZING POINT: Not available

VAPOR PRESSURE: Not available

VAPOR DENSITY: Not available

SPECIFIC GRAVITY: Not available

WATER SOLUBILITY: slightly soluble

PH: 5.0-7.5 (saturated solution)

VOLATILITY: Not available

ODOR THRESHOLD: Not available

EVAPORATION RATE: Not available

COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

SOLVENT SOLUBILITY:

Soluble: alcohol

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 products or combustion: oxides of carbon, oxides of nitrogen, oxides of sulfur

POLYMERIZATION: Will not polymerize.

11. TOXICOLOGICAL INFORMATION

PENICILLIN G BENZATHINE, TETRAHYDRATE:

TARGET ORGANS: immune system (sensitizer)

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: immune system disorders or allergies

ADDITIONAL DATA: May cross the placenta. May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

14. TRANSPORT INFORMATION

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

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: Yes

CHRONIC: Yes

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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