

10 P. 1



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 Option 5
TECHNICAL ASSISTANCE:
1-800-776-3637 Option 5

SUBSTANCE: APLISOL(R)

TRADE NAMES/SYNONYMS:

NDC# 64029-4525-1 (1 mL Vial); 64029-4525-2 (5 mL Vial)

CREATION DATE: Jul 28 2004

REVISION DATE: Sep 30 2004

2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: TUBERCULIN PPD

CAS NUMBER: Not assigned.

PERCENTAGE: 5 TU per 0.1/mL

COMPONENT: INERT INGREDIENTS

CAS NUMBER: Not assigned.

PERCENTAGE: balance

3. HAZARDS IDENTIFICATION

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

EMERGENCY OVERVIEW:

PHYSICAL FORM: liquid

MAJOR HEALTH HAZARDS: No significant target effects reported.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

SKIN CONTACT:



#10 p. 2

SHORT TERM EXPOSURE: allergic reactions

LONG TERM EXPOSURE: allergic reactions

EYE CONTACT:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

INGESTION:

SHORT TERM EXPOSURE: no information on significant adverse effects

LONG TERM EXPOSURE: no information on significant adverse effects

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: 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.

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. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

FLASH POINT: >200 F (>93.3 C)

FLAMMABILITY CLASS (OSHA): IIIB

HAZARDOUS COMBUSTION PRODUCTS:

Thermal decomposition products or combustion: oxides of carbon

6. ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Stop leak if possible without personal risk. Small spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

7. HANDLING AND STORAGE

STORAGE: Store and handle in accordance with all current regulations and standards. Store between 2

10 P. 3

C and 8 C. Avoid contact with light. See original container for storage recommendations. Keep separated from incompatible substances.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

APLISOL(R):

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.

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: clear

ODOR: Not available

BOILING POINT: Not available

FREEZING POINT: Not available

VAPOR PRESSURE: Not available

VAPOR DENSITY: Not available

SPECIFIC GRAVITY: Not available

WATER SOLUBILITY: soluble

PH: Not available

VOLATILITY: Not available

ODOR THRESHOLD: Not available

EVAPORATION RATE: Not available

COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

#10 p.4

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

POLYMERIZATION: Will not polymerize.

11. TOXICOLOGICAL INFORMATION

APLISOL(R):

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: allergic reactions

ADDITIONAL DATA: This product is administered intradermally as an aid in the detection of infection with Mycobacterium tuberculosis. An inflammatory response in the skin with redness and swelling may occur at the injection site. Highly sensitive individuals may experience blistering, ulceration and necrosis. Refer to the current package insert for additional information.

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

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.

#10 p.5

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): All the components of this substance are listed on or are exempt from the inventory.

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

16. OTHER INFORMATION

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.

I-250934 C-64029452501
I-250935 C-64029452502
I-653303 C-42023010401
I-653304 C-42023010405