



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: TIGAN INJECTION 100 MG/ML

TRADE NAMES/SYNONYMS:

TRIMETHOBENZAMIDE HYDROCHLORIDE; NDC #: 61570-540-02 (2 ml Ampoules); NDC #: 61570-541-20 (Vials)

PRODUCT USE: pharmaceutical

CREATION DATE: Jul 28 2004

REVISION DATE: Oct 13 2004

2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: TRIMETHOBENZAMIDE HYDROCHLORIDE

CAS NUMBER: 554-92-7

PERCENTAGE: 10

COMPONENT: INERT EXCIPIENTS

CAS NUMBER: Not assigned.

PERCENTAGE: balance

3. HAZARDS IDENTIFICATION

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

EMERGENCY OVERVIEW:

COLOR: colorless

PHYSICAL FORM: solution

MAJOR HEALTH HAZARDS: central nervous system depression, allergic reactions

POTENTIAL HEALTH EFFECTS:



INHALATION:

SHORT TERM EXPOSURE: irritation, allergic reactions, changes in blood pressure, diarrhea, headache, drowsiness, dizziness, disorientation, muscle cramps, blurred vision, blood disorders, liver damage, convulsions, coma

LONG TERM EXPOSURE: allergic reactions

SKIN CONTACT:

SHORT TERM EXPOSURE: irritation, allergic reactions

LONG TERM EXPOSURE: allergic reactions

EYE CONTACT:

SHORT TERM EXPOSURE: irritation

LONG TERM EXPOSURE: no information is available

INGESTION:

SHORT TERM EXPOSURE: gastrointestinal irritation, allergic reactions, changes in blood pressure, diarrhea, headache, drowsiness, dizziness, disorientation, muscle cramps, blurred vision, blood disorders, liver damage, convulsions, coma

LONG TERM EXPOSURE: allergic reactions

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.

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

FLASH POINT: aqueous solution

HAZARDOUS COMBUSTION PRODUCTS:

Thermal decomposition products or combustion: chlorine, oxides of nitrogen, 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 at 25 C. See original container for storage recommendations. Keep separated from incompatible substances.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

TIGAN INJECTION 100 MG/ML:

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

COLOR: colorless

PHYSICAL FORM: solution

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: Not available
PH: 5.0
VOLATILITY: Not available
ODOR THRESHOLD: Not available
EVAPORATION RATE: Not available
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 products or combustion: chlorine, oxides of nitrogen, oxides of carbon

POLYMERIZATION: Will not polymerize.

11. TOXICOLOGICAL INFORMATION

TRIMETHOBENZAMIDE HYDROCHLORIDE:

TOXICITY DATA:

1600 mg/kg oral-mouse LD50

ACUTE TOXICITY LEVEL:

Moderately Toxic: ingestion

TARGET ORGANS: immune system (sensitizer), central nervous system

ADDITIONAL DATA: Interactions with drugs may occur. May impair performance of tasks requiring alertness.

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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