

# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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INC.

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## SUBSTANCE: OXYTETRACYCLINE HYDROCHLORIDE

TRADE NAMES/SYNONYMS:

LIQUAMYCIN INJECTABLE

CHEMICAL FAMILY: antibiotic/antiseptic

CREATION DATE: Jun 19 1986

REVISION DATE: Mar 17 2005

## 2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: OXYTETRACYCLINE HYDROCHLORIDE

CAS NUMBER: 2058-46-0

EC NUMBER (EINECS): 218-161-2

PERCENTAGE: 100

## 3. HAZARDS IDENTIFICATION

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

EMERGENCY OVERVIEW:

CHANGE IN APPEARANCE: darkens on exposure to moisture, hygroscopic

COLOR: yellow

PHYSICAL FORM: crystals, powder

ODOR: odorless

MAJOR HEALTH HAZARDS: No significant target effects reported.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: irritation

LONG TERM EXPOSURE: no information is available

SKIN CONTACT:

SHORT TERM EXPOSURE: irritation

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

EYE CONTACT:

SHORT TERM EXPOSURE: no information is available

LONG TERM EXPOSURE: no information is available

INGESTION:

SHORT TERM EXPOSURE: vomiting, digestive disorders, irregular heartbeat

LONG TERM EXPOSURE: tooth discoloration, kidney damage, tumors

CARCINOGEN STATUS:

OSHA: No

NTP: No

IARC: No

## 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 swallowed, drink plenty of water, do NOT induce vomiting. Get immediate medical attention. Induce vomiting only at the instructions of a physician. Do not give anything by mouth to unconscious or convulsive person.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage, activated charcoal slurry and catharsis.

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## 5. FIRE FIGHTING MEASURES

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**FIRE AND EXPLOSION HAZARDS:** Negligible fire hazard.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**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.

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## 6. ACCIDENTAL RELEASE MEASURES

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**WATER RELEASE:**

Subject to California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Keep out of water supplies and sewers.

**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.

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## 7. HANDLING AND STORAGE

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

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## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

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**EXPOSURE LIMITS:**

**OXYTETRACYCLINE HYDROCHLORIDE:**

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 dust and mist respirator with a full facepiece.

Any air-purifying respirator with a full facepiece and a high-efficiency particulate filter.

Any powered, air-purifying respirator with a tight-fitting facepiece and a high-efficiency particulate filter.

**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.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

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**PHYSICAL STATE:** solid

**COLOR:** yellow

**CHANGE IN APPEARANCE:** darkens on exposure to moisture, hygroscopic

**PHYSICAL FORM:** crystals, powder

**ODOR:** odorless

**TASTE:** bitter taste

**MOLECULAR WEIGHT:** 496.94  
**MOLECULAR FORMULA:** C<sub>22</sub>-H<sub>24</sub>-N<sub>2</sub>-O<sub>9</sub>.H-CL  
**BOILING POINT:** Not applicable  
**MELTING POINT:** Not available  
**DECOMPOSITION POINT:** 356 F (180 C)  
**VAPOR PRESSURE:** Not applicable  
**VAPOR DENSITY:** Not applicable  
**SPECIFIC GRAVITY:** Not available  
**WATER SOLUBILITY:** soluble  
**PH:** 2.5 (1% solution)  
**VOLATILITY:** Not applicable  
**ODOR THRESHOLD:** Not available  
**EVAPORATION RATE:** Not applicable  
**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available  
**SOLVENT SOLUBILITY:**  
**Soluble:** ethanol, methanol  
**Insoluble:** ether, chloroform

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## 10. STABILITY AND REACTIVITY

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**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:** bases

**OXYTETRACYCLINE HYDROCHLORIDE:**  
**SOLUTIONS HAVING PH BELOW 2:** Diminished potency.  
**ALKALI HYDROXIDE SOLUTIONS:** Rapidly destroyed.

**HAZARDOUS DECOMPOSITION:**  
Thermal decomposition products: acid halides, oxides of nitrogen

**POLYMERIZATION:** Will not polymerize.

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## 11. TOXICOLOGICAL INFORMATION

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**OXYTETRACYCLINE HYDROCHLORIDE:**

**TOXICITY DATA:**

800 mg/kg subcutaneous-rat LD50; 302 mg/kg intravenous-rat LD50; 6696 mg/kg oral-mouse LD50; 600 mg/kg subcutaneous-mouse LD50; 100 mg/kg intravenous-mouse LD50; 100 mg/kg intravenous-dog LDLo; 80 mg/kg intravenous-rabbit LDLo; 108 gm/kg/14 day(s) continuous oral-rat TDLo; 129 gm/kg/14 day(s) continuous oral-mouse TDLo; 21000 mg/kg/10 day(s) intermittent oral-mouse TDLo; 21000 mg/kg/10 day(s) intermittent oral-mouse TDLo; 13250 mg/kg/10 day(s) intermittent oral-mouse TDLo; 7200 mg/kg/6 day(s) intermittent oral-rat TDLo; 12000 mg/kg/10 day(s) intermittent oral-rat TDLo

**CARCINOGEN STATUS:** In 2 year feeding studies, there was equivocal evidence of carcinogenicity for male and female rats and no evidence of carcinogenicity for male or female mice (NTP TR 315).

**ACUTE TOXICITY LEVEL:**

Slightly Toxic: ingestion

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** kidney disorders, liver disorders

**TUMORIGENIC DATA:**

1802 gm/kg oral-rat TDLo/2 year(s); 2163000 mg/kg oral-rat TDLo/103 week(s) continuous; 1802500 mg/kg oral-rat TDLo/103 week(s) continuous

**MUTAGENIC DATA:**

DNA adduct - *Bacillus subtilis* 10 umol/L; DNA adduct - other microorganisms 10 mg/L; DNA adduct - other microorganisms 10 umol/L; micronucleus test - mouse oral 100 mg/kg 24 hour(s)-intermittent; specific locus test - mouse lymphocyte 200 mg/L; DNA adduct - mammal lymphocyte 20 mg/L; unscheduled DNA synthesis - mammal lymphocyte 20 mg/L

**REPRODUCTIVE EFFECTS DATA:**

20 mg/kg parenteral-woman TDLo 20 week(s) pregnant female continuous; 11250 mg/kg oral-rat TDLo 6-15 day(s) pregnant female continuous; 12 gm/kg oral-rat TDLo 6-15 day(s) pregnant female continuous; 21 gm/kg oral-mouse TDLo 6-15 day(s) pregnant female continuous; 900 mg/kg subcutaneous-mouse TDLo 10-18 day(s) pregnant female continuous; 21 gm/kg oral-mouse TDLo 6-15 day(s) pregnant female continuous; 13.3 gm/kg oral-mouse TDLo 6-15 day(s) pregnant female continuous; 12 gm/kg oral-rat TDLo 6-15 day(s) pregnant female continuous

**ADDITIONAL DATA:** Interactions with drugs may occur.

**HEALTH EFFECTS:**

**INHALATION:**

**ACUTE EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: No data available. Dusts may irritate mucous membranes.

**CHRONIC EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: No data available.

**SKIN CONTACT:****ACUTE EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: No data available. However, oxytetracycline may cause skin irritation in some individuals. There is a possibility of sensitization reactions in individuals who have exhibited hypersensitivity to tetracyclines.

**CHRONIC EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: When used topically, oxytetracycline hydrochloride may cause sensitization. However, repeated oral exposures to oxytetracycline has produced dermatitis, photo-onycholysis and porphyria-like cutaneous changes.

**EYE CONTACT:****ACUTE EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: No data available. However 1% tetracycline in an ointment caused no detectable injury to rabbit's eyes.

**CHRONIC EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: No data available.

**INGESTION:****ACUTE EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: A dose of 6696 mg/kg was lethal in mice. Tetracyclines may cause nausea, gastrointestinal irritation, vomiting, abdominal pain, esophageal ulcers, epigastric pain and burning, diarrhea, dysphagia, enterocolitis, anorexia, uremia, pancytopenia, acidosis, hyperkalemia, and cardiac arrhythmias. Large oral doses may cause hypersensitivity, phototoxic, nephrotoxic, and hepatotoxic reactions in humans previously exposed to tetracyclines.

**CHRONIC EXPOSURE:**

OXYTETRACYCLINE HYDROCHLORIDE: In 14 day feed studies, a reduction in mean body weights and feed consumption was noted in rats and mice at 100,000 ppm. The study indicated that males were more sensitive than females to the effects; no deaths were reported. In 13 week studies, mean body weight reduction was noted in mice at 50,000 ppm. No deaths occurred but a fatty metamorphosis of the liver was observed in male rats. In a 2 year study, no significant toxic effect was noted, nor was survival affected. However, pheochromocytomas of the adrenal gland occurred with a positive trend in male rats and an increased incidence of adenomas of the pituitary gland in female rats was recorded. An increased incidence of mammary adenofibromas was observed in female rats. The average survival time for rats receiving oxytetracycline hydrochloride was 11% greater than that of the controls. Reproductive effects have been reported in animals. Use of oxytetracyclines is associated with 3 kinds of renal disease: Acute non-oliguric renal failure in persons with pancreatitis or fatty liver; uremia, in persons with previously impaired renal function; and a falconi-like syndrome, usually associated with outdated or degraded tetracyclines. Tetracyclines tend to be deposited in the bones and the teeth at sites of active calcification. Prolonged use has caused discoloration of the teeth and a 40% depression of bone growth in neonates, infants and children. Sensitization reactions may occur, characterized by burning of the eyes, jaundice, fatty liver, cheilosis, glossitis, pruritus, conjunctivitis, dermatitis, eosinophilia, leukocytosis, thrombocytopenic purpura, and photosensitivity manifested by exaggerated sunburn. Cross-sensitization is common among the various tetracyclines. In persons with impaired renal function, high serum levels of tetracycline may lead to azotemia, hyperphosphatemia, acidosis, and in infants tense bulging of the fontanel. Tetracyclines may cause benign intracranial hypertension with papilledema and retinal hemorrhages; this may occur more frequently in children than adults. Pregnant women appear to be more susceptible to severe hepatic damage. Tetracyclines may interfere with Vitamin K synthesis and blood coagulation. Repeated use of antibiotics may lead to the development of vaginal, oral, pharyngeal, intestinal and systemic suprainfections due to overgrowth of organisms not affected by the antibiotic agent. In some cases, these organisms produce toxins that cause severe vomiting, diarrhea and circulatory collapse.

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## 12. ECOLOGICAL INFORMATION

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**ECOTOXICITY DATA:**

**FISH TOXICITY:** <200000 ug/L 96 hour(s) LC50 (Mortality) Lake trout, siscowet (*Salvelinus namaycush*)

**ENVIRONMENTAL SUMMARY:** Harmful to aquatic life.

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## 13. DISPOSAL CONSIDERATIONS

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Dispose in accordance with all applicable regulations.

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## 14. TRANSPORT INFORMATION

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

**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:** No classification assigned.

**LAND TRANSPORT ADR:** No classification assigned.

**LAND TRANSPORT RID:** No classification assigned.

**AIR TRANSPORT IATA:** No classification assigned.

**AIR TRANSPORT ICAO:** No classification assigned.

**MARITIME TRANSPORT IMDG:** No classification assigned.

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## 15. REGULATORY INFORMATION

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### 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:**

Known to the state of California to cause the following:

**Oxytetracycline hydrochloride (internal use)**

Developmental toxicity (Oct 01, 1991)

### CANADIAN REGULATIONS:

**WHMIS CLASSIFICATION:** Not determined.

### EUROPEAN REGULATIONS:

**EC CLASSIFICATION (CALCULATED):** Not determined.

### GERMAN REGULATIONS:

**WATER HAZARD CLASS (WGK):**

**STATE OF CLASSIFICATION:** Annex 3

**CLASSIFICATION UNDER HAZARD TO WATER:** 2

### NATIONAL INVENTORY STATUS:

**U.S. INVENTORY (TSCA):** Listed on inventory.

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

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## 16. OTHER INFORMATION

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