Material Safety Data Sheet
Tetracycline Hydrochloride

Section 1 - Chemical Product and Company Identification

**MSDS Name:** Tetracycline Hydrochloride

**Company Identification:**
Teva Sicor Pharmaceuticals, Inc.
11 Hughes
Irvine, CA 92618-1902

For information, call: 1-800-729-9991
Emergency Number: 1-800-729-9991
For CHEMTREC assistance, call: 800-424-9300
For International CHEMTREC assistance, call: 703-527-3887

Section 2 - Composition, Information on Ingredients

<table>
<thead>
<tr>
<th>CAS#</th>
<th>Chemical Name</th>
<th>Percent</th>
<th>EINECS/ELINCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-75-5</td>
<td>Tetracycline Hydrochloride</td>
<td>100.0%</td>
<td>200-593-8</td>
</tr>
</tbody>
</table>

Section 3 - Hazards Identification

**EMERGENCY OVERVIEW**

Appearance: yellow solid.

**Warning!** Causes eye irritation. May cause allergic skin reaction. May cause digestive tract irritation with nausea, vomiting, and diarrhea. Light sensitive. Air sensitive. May cause liver and kidney damage. Moisture sensitive. Ingestion may result in an allergic reaction. May cause reproductive and fetal effects.

**Target Organs:** Kidneys, liver, skeletal structures, teeth.

**Potential Health Effects**

**Eye:** Causes eye irritation.

**Skin:** May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.

**Ingestion:** May cause gastrointestinal irritation with nausea, vomiting and diarrhea. May cause liver and kidney damage. Substance may cause hypersensitivity reactions and liver, teeth and bone abnormalities. May cause brown discoloration of teeth enamel.

**Inhalation:** Excessive inhalation may cause minor respiratory irritation. May cause effects similar to those described for ingestion.
**Chronic:** May cause fetal effects. Adverse reproductive effects have been reported in animals. Laboratory experiments have resulted in mutagenic effects.

### Section 4 - First Aid Measures

**Eyes:** Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.

**Skin:** Get medical aid if irritation develops or persists. Wash clothing before reuse. Flush skin with plenty of soap and water.

**Ingestion:** If victim is conscious and alert, give 2-4 cupfuls of milk or water. Never give anything by mouth to an unconscious person. Get medical aid immediately.

**Inhalation:** Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.

**Notes to Physician:** Treat symptomatically and supportively.

### Section 5 - Fire Fighting Measures

**General Information:** As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Combustion generates toxic fumes. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Runoff from fire control or dilution water may cause pollution.

**Extinguishing Media:** Use agent most appropriate to extinguish fire. Do NOT get water inside containers. In case of fire, use carbon dioxide, dry chemical powder or appropriate foam.

**Flash Point:** Not available.

**Autoignition Temperature:** Not applicable.

**Explosion Limits, Lower:** Not available.

**Upper:** Not available.

**NFPA Rating:** (estimated) Health: 2; Flammability: 0; Instability: 1

### Section 6 - Accidental Release Measures

**General Information:** Use proper personal protective equipment as indicated in Section 8.

**Spills/Leaks:** Vacuum or sweep up material and place into a suitable disposal container. Clean up spills immediately, observing precautions in the Protective Equipment section. Avoid generating dusty conditions. Provide ventilation. Place under an inert atmosphere. Do not get water inside containers.

### Section 7 - Handling and Storage

**Handling:** Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Minimize dust generation and
accumulation. Avoid contact with skin and eyes. Keep container tightly closed. Avoid ingestion and inhalation. Store protected from light. Handle under an inert atmosphere. Store protected from air. Do not allow contact with water. Keep from contact with moist air and steam.

**Storage:** Store in a cool, dry, well-ventilated area away from incompatible substances. Do not expose to air. Store protected from moisture. Store protected from light. Store under an inert atmosphere.

### Section 8 - Exposure Controls, Personal Protection

**Engineering Controls:** Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

**Exposure Limits**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>NIOSH</th>
<th>OSHA - Final PELs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline Hydrochloride</td>
<td>none listed</td>
<td>none listed</td>
<td>none listed</td>
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</table>

**OSHA Vacated PELs:** Tetracycline Hydrochloride: No OSHA Vacated PELs are listed for this chemical.

**Personal Protective Equipment**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

**Skin:** Wear appropriate protective gloves and clothing to prevent skin exposure.

**Clothing:** Wear appropriate protective clothing to minimize contact with skin.

**Respirators:** Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### Section 9 - Physical and Chemical Properties

**Physical State:** Solid

**Appearance:** yellow

**Odor:** none reported

**pH:** 2.1-2.3 (2% sol.)

**Vapor Pressure:** Not available.

**Vapor Density:** Not available.

**Evaporation Rate:** Not available.

**Viscosity:** Not available.

**Boiling Point:** Not available.

**Freezing/Melting Point:** 213.9 deg C

**Decomposition Temperature:** 213.9 deg C

**Solubility:** Soluble in water.

**Specific Gravity/Density:** Not available.
Molecular Formula: C22H24N2O8.HCl
Molecular Weight: 480.90

Section 10 - Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures. Substance undergoes color change upon exposure to light and air.
Conditions to Avoid: High temperatures, incompatible materials, light, dust generation, moisture, exposure to air, excess heat, strong oxidants.
Incompatibilities with Other Materials: Oxidizing agents, moisture, air.
Hazardous Decomposition Products: Hydrogen chloride, nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.
Hazardous Polymerization: Has not been reported

Section 11 - Toxicological Information

RTECS#: 
CAS# 64-75-5: Q19100000
LD50/LC50: 
CAS# 64-75-5:
  Oral, mouse: LD50 = 2759 mg/kg;
  Oral, rat: LD50 = 6443 mg/kg;

Carcinogenicity:
CAS# 64-75-5: Not listed by ACGIH, IARC, NTP, or CA Prop 65.

Epidemiology: No information found
Teratogenicity: Teratogenic effects have occurred in experimental animals.
Reproductive Effects: Based upon 1944 pregnancy exposures, possible associations with congenital anomalies found in 61 infants: hypospadias (5 cases), inguinal hernia (47 cases), limb hypoplasia (6 cases), and clubfoot (3 cases). Adverse reproductive effects have occurred in experimental animals.
Mutagenicity: Mutagenic effects have occurred in humans.
Neurotoxicity: No information found
Other Studies:

Section 12 - Ecological Information

No information available.

Section 13 - Disposal Considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must
consult state and local hazardous waste regulations to ensure complete and accurate classification.

**RCRA P-Series:** None listed.

**RCRA U-Series:** None listed.

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<thead>
<tr>
<th>Section 14 - Transport Information</th>
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<tbody>
<tr>
<td><strong>US DOT</strong></td>
</tr>
<tr>
<td><strong>Shipping Name:</strong> CARBON DIOXIDE, SOLID USED FOR DIAGNOSTIC OR TREATMENT PURPOSE</td>
</tr>
<tr>
<td><strong>Hazard Class:</strong> 9</td>
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<tr>
<td><strong>UN Number:</strong> UN1845</td>
</tr>
<tr>
<td><strong>Packing Group:</strong> III</td>
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<tr>
<th>Section 15 - Regulatory Information</th>
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**US FEDERAL**

**TSCA**
CAS# 64-75-5 is listed on the TSCA inventory.

**Health & Safety Reporting List**
None of the chemicals are on the Health & Safety Reporting List.

**Chemical Test Rules**
None of the chemicals in this product are under a Chemical Test Rule.

**Section 12b**
None of the chemicals are listed under TSCA Section 12b.

**TSCA Significant New Use Rule**
None of the chemicals in this material have a SNUR under TSCA.

**CERCLA Hazardous Substances and corresponding RQs**
None of the chemicals in this material have an RQ.

**SARA Section 302 Extremely Hazardous Substances**
None of the chemicals in this product have a TPQ.

**SARA Codes**
CAS # 64-75-5: delayed.

**Section 313**
This material contains Tetracycline Hydrochloride (CAS# 64-75-5, 100.0%), which is subject to the reporting requirements of Section 313 of SARA Title III and 40 CFR

**Clean Air Act:**
This material does not contain any hazardous air pollutants.
This material does not contain any Class 1 Ozone depleters.
This material does not contain any Class 2 Ozone depleters.

**Clean Water Act:**
None of the chemicals in this product are listed as Hazardous Substances under the CWA.
None of the chemicals in this product are listed as Priority Pollutants under the CWA.
None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

**OSHA:**
None of the chemicals in this product are considered highly hazardous by OSHA.

**STATE**
CAS# 64-75-5 is not present on state lists from CA, PA, MN, MA, FL, or NJ.

**California Prop 65**
WARNING: This product contains Tetracycline Hydrochloride, a chemical known to the state of California to cause developmental reproductive toxicity.
California No Significant Risk Level: None of the chemicals in this product are listed.

**European/International Regulations**
**European Labeling in Accordance with EC Directives**

**Hazard Symbols:**
- XN

**Risk Phrases:**
- R 36 Irritating to eyes.
- R 63 Possible risk of harm to the unborn child.

**Safety Phrases:**
- S 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
- S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**WGK (Water Danger/Protection)**
CAS# 64-75-5: No information available.

**Canada - DSL/NDSL**
CAS# 64-75-5 is listed on Canada's DSL List.

**Canada - WHMIS**
This product has a WHMIS classification of D2A.
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

**Canadian Ingredient Disclosure List**

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**Section 16 - Additional Information**

**MSDS Creation Date:** 11/28/2007