



Humco Holding Group, Inc.
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24-Hour Emergency Number (CHEMTREC)
USA- 800-424-9300

All non-emergency calls should be directed to
Customer Service at 800-662-3435

NAME: TETRACYCLINE HYDROCHLORIDE, USP **SDS NO. 8047**

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Tetracycline Hydrochloride, USP

Synonyms: (4S,4aS,5aS,6S,12aS)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride.

Recommended Use: Active Pharmaceutical Ingredient

Manufacturer by: Humco Holding Group, Inc.

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2. HAZARD IDENTIFICATION

Pictogram:	
Classification:	Skin Irritation (Category 2) Eye Irritation (Category 2A) Toxic to Reproduction (Effects on or via lactation) Toxic to Reproduction (Category 1A) Specific Target Organ Toxicity - Single Exposure (Category 3)
Signal Word:	Danger
Hazard Statements:	Causes skin irritation. Causes serious eye irritation.

	<p>May cause harm to breast-fed children.</p> <p>May damage fertility or the unborn child.</p> <p>Exposure may produce an allergic reaction.</p> <p>May cause respiratory irritation.</p>
Precautionary Statements	<p>Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection. Do not breathe dusts or mists. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid breathing dust, fume, gas, mist, vapors, and spray. In case of inadequate ventilation wear respiratory protection.</p> <p>Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.</p> <p>IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.</p> <p>IF EXPOSED OR CONCERNED: Get medical advice/attention.</p> <p>Storage: Store locked up.</p> <p>Disposal: Dispose of contents and/or container in accordance with local regulations.</p>

3. COMPOSITION / INGREDIENTS

CHEMICAL NAME	CAS#
TETRACYCLINE HYDROCHLORIDE, USP	64-75-5

4. FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS: Not expected to present a significant hazard under anticipated conditions of normal use.

5. FIRE-FIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition.

Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS: Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight, light-resistant containers.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Tetracycline Hydrochloride 64-75-5	N/L	N/L	N/L	N/L

EXPOSURE GUIDELINES: Consult local authorities for provincial or state exposure limits

PERSONAL PROTECTIVE EQUIPMENT: Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or 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.

SPECIFIC ENGINEERING CONTROLS: Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Yellow Crystalline Powder	Upper/Lower Flammability:	Not determined
Odor:	Not determined	Vapor Pressure	< 0.0000001 kPa (25°C)
Odor Threshold:	Not determined	Vapor Density:	Not determined
pH:	1.8 - 2.8 (1%)	Relative Density:	0.72
Melting point /Freezing Point:	(214 - 223)°C, (417.2-433.4)°F (Decomposes)	Solubilities:	Not determined
Boiling point/range:	Not determined	Partition coefficient: n-octanol/water:	Not determined
Flash point	Not determined	Auto-ignition temperature	Not determined
Evaporation rate	Not determined	Decomposition Temperature:	Not determined
Flammability:	Not determined	Viscosity	Not determined

10. STABILITY AND REACTIVITY

REACTIVITY: Not established

STABILITY: Stable under recommended storage conditions

MATERIALS TO AVOID: Strong oxidants, solutions of metal cations, strong bases.

HAZARDOUS DECOMPOSITION PRODUCTS: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, chloride and other gases may occur.

HAZARDOUS POLYMERIZATION: Will not occur

POSSIBILITY OF HAZARDOUS REACTION: Not established

CONDITIONS TO AVOID: Moisture, sunlight and extreme temperatures

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Oral: Rat: LD50 (mg/Kg): 6443 mg/kg

Dermal: Rabbit: LD50: Not available

Inhalation: Rat: LD50: Not available

SKIN CORROSION/IRRITATION: Not available

SERIOUS EYE DAMAGE/EYE IRRITATION: Not available

RESPIRATORY OR SKIN SENSITIZATION: Cross sensitivity: Persons sensitive to any of the tetracyclines may be sensitive to this material also Hypersensitivity to the tetracyclines is much less common than to the beta lactams, but hypersensitivity reactions, including rashes, fixed drug eruptions, exfoliative dermatitis, toxic epidermal necrolysis, drug fever, pericarditis, angioedema, urticaria, and asthma have been reported; anaphylaxis has occurred very rarely.

GERM CELL MUTAGENICITY: Genotoxicity tests have shown mixed results. Data from germ cell mutagenicity tests were not found. Due to lack of data the classification is not possible.

CARCINOGENICITY

OSHA: Not listed.

NTP: Not listed.

IARC: Not listed.

California Proposition 65: This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: TETRACYCLINE HYDROCHLORIDE.

REPRODUCTIVE TOXICITY: The therapeutic use of tetracyclines during the last half of pregnancy may cause permanent discoloration of the teeth, incomplete development or lack of enamel, and inhibition of skeletal growth in the fetus. In addition, fatty infiltration of the liver, leading to damage or failure, may occur in pregnant women. They should also be avoided during breast feeding and in children up to the age of 8, or according to the BNF, 12 years. Use in pregnancy, potentially during breast feeding, or in childhood, may result in impaired bone growth and permanent discoloration of the child's teeth. The American Academy of Pediatrics states that, after use of tetracycline by breast-feeding mothers, there is negligible absorption by the infant and that tetracycline is therefore usually compatible with breast feeding. However, licensed product information states that adverse effects including permanent tooth discoloration and enamel hypoplasia may occur in breast-fed infants and that breast feeding is contra-indicated during treatment with tetracyclines.

SPECIFIC TARGET ORGAN TOXICITY-SINGLE EXPOSURE: May cause respiratory irritation.

SPECIFIC TARGET ORGAN TOXICITY-REPEATED EXPOSURE: Not Available.

ASPIRATION HAZARDS: Not Available.

SIGNS AND SYMPTOMS OF EXPOSURE: Not expected to present a significant hazard under anticipated conditions of normal use.

May cause nausea, vomiting, diarrhea, oesophageal ulceration, glossitis, stomatitis, dysphagia; oral candidiasis, vulvovaginitis, pruritus ani, renal dysfunction, increased liver enzymes, hepatotoxicity, permanent discoloration of the teeth and enamel hypoplasia; nail discoloration, onycholysis, abnormal

pigmentation of the skin, conjunctiva, oral mucosa, tongue and internal organs; intracranial hypertension with headache, dizziness, tinnitus, visual disturbances, papilloedema; muscle weakness; rashes, fixed drug eruptions, exfoliative dermatitis, toxic epidermal necrolysis, drug fever, pericarditis, angioedema, urticarial, asthma; thrombophlebitis, agranulocytosis, aplastic anaemia, haemolytic anaemia, eosinophilia, neutropenia, thrombocytopenia, hypofibrinemia, Fanconi-type syndrome. Symptoms related to the physical, chemical, and toxicological characteristics: Tetracyclines: Diarrhea. Nausea. Vomiting. Dizziness. Lightheadedness. Unsteadiness. Joint pain. Cramps or burning of the stomach. Increased sensitivity of skin to sunlight. Sore mouth or tongue. Discolored tongue. Bone or tooth discoloration. Itching of the rectal or genital area. Delayed and immediate effects of exposure: Tetracyclines: Superinfections. Antibiotic-associated colitis. Liver toxicity. Cross sensitivity: Persons sensitive to any of the tetracyclines may be sensitive to this material also. Medical conditions aggravated by exposure: Impaired kidney function. Impaired liver function. Systemic lupus erythematosus. Myasthenia gravis.

POTENTIAL HEALTH EFFECTS

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin: May be harmful if absorbed through skin. Causes skin irritation.

Eyes: Causes serious eye irritation.

12. ECOLOGICAL INFORMATION

Acute or chronic aquatic toxicity:	No specific information available, but material is not intended to be released to the environment.
Chemical degradation:	Not determined.
Biodegradation:	Not determined.
Bioaccumulation potential	Not determined.
Adsorption studies or leaching studies:	Not determined.
Other adverse effects	Not determined.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local laws and regulations. Avoid release into environment.

14. TRANSPORT INFORMATION

DOT Hazard Classification:	NOT APPLICABLE
UN number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group number:	Not applicable

Environmental hazards:	Not applicable
Special precautions:	Do not freeze, avoid extreme heat

15. REGULATORY INFORMATION

Not determined

16. OTHER INFORMATION

The information in this SDS is considered current and reliable. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal are beyond Humco's control, it is the responsibility of the user to determine safe conditions for use and to assume liability for loss, damage, or expenses arising from improper use. No warranty expressed or implied regarding the product described herein will be created by or inferred from any statement or omission. Various agencies may have specific regulations concerning the transportation, handling, storage, use or disposal of this product which may not be reflected in the SDS. The user should review these regulations to ensure full compliance.