

Mutual Pharmaceutical

DOXYCYCLINE HYCLATE

COMMON NAME: Doxycycline Hyclate  
 CAT #: 22600  
 UNITS PACKAGE SIZE: 200 mg  
 MANUFACTURER: MUTUAL PHARMACEUTICAL CO., INC.  
 EMERGENCY AND INFORMATION TELEPHONE CALLS: (301) 881-0666  
 RESPONSIBLE PARTY: William M. Heller  
 DATE PREPARED: 07-15-88  
 WARNING STATEMENT: WARNING! REFERENCE STANDARD; NOT FOR HUMAN CONSUMPTION; AVOID INGESTION, INHALATION, SKIN CONTACT. FOR CHEMICAL TEST AND ASSAY USE ONLY.

SECTION 1 - IDENTITY

COMMON NAME: Doxycycline Hyclate  
 SYNONYMS: n/a  
 CAS NUMBER: 24390-14-5 (hyclate); 564-25-0 (doxycycline)  
 RTECS NUMBER: QI8650000 (doxycycline)  
 CHEMICAL NAME: 2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1, 11-dioxo-, monohydrochloride compound with ethanol (2:1), monohydrate, [4S-(4a,4aa,5aa,6a,12aa)]-  
 CHEMICAL FAMILY: Tetracycline  
 THERAPEUTIC CATEGORY: Antibacterial  
 FORMULA: (C22H24N2O8.HCl).2.C2H6O.H2O

SECTION 2 - HAZARDOUS INGREDIENTS

PRINCIPAL HAZARDOUS COMPONENT(S) [Chemical & Common name(s)]	PERCENT	THRESHOLD LIMIT VALUE (UNITS)
Doxycycline Hyclate	Pure Material	Not established

SECTION 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS (Fire & Explosion Data)

BOILING POINT: n/a  
 SPECIFIC GRAVITY (H2O = 1): n/a  
 VAPOR PRESSURE (mm Hg): n/a  
 PERCENT VOLATILE BY VOLUME (%): n/a  
 VAPOR DENSITY (AIR = 1): n/a  
 EVAPORATION RATE: n/a  
 SOLUBILITY IN WATER: Soluble  
 REACTIVITY IN WATER: n/a  
 APPEARANCE AND ODOR: Light yellow crystalline powder; slight ethanolic odor  
 FLASH POINT: n/a  
 FLAMMABLE LIMITS IN AIR % BY VOLUME:  
 LOWER: n/a  
 UPPER: n/a  
 EXTINGUISHER MEDIA: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.  
 AUTO-IGNITION TEMPERATURE: n/a  
 SPECIAL FIRE FIGHTING PROCEDURES: As with all fires, evacuate personnel to a safe area. Firefighters should use self contained breathing equipment and protective clothing.  
 UNUSUAL FIRE AND EXPLOSION HAZARDS: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity. Emits toxic fumes under fire conditions. When heated to decomposition material emits toxic fumes.

SECTION 4 - PHYSICAL HAZARDS

STABILITY: Stable  
 CONDITIONS TO AVOID: Material is stable from a safety point of view.  
 INCOMPATIBILITY (MATERIALS TO AVOID): n/a  
 HAZARDOUS DECOMPOSITION PRODUCTS: When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.  
 HAZARDOUS POLYMERIZATION: Will Not Occur

SECTION 5 - HEALTH HAZARDS

THRESHOLD LIMIT VALUE: None established  
 SIGNS AND SYMPTOMS OF OVEREXPOSURE:  
 [Doxycycline CAS RN: 564-25-0  
 LD50: 378 mg/Kg intraperitoneal-rat;  
 LD50: 228 mg/Kg intravenous-rat;  
 LD50: 1870 mg/Kg oral-mouse;  
 LD50: 410 mg/Kg intraperitoneal-mouse;  
 LD50: 241 mg/Kg intravenous-mouse;  
 Mutation Data [RTECS]]  
 The usual adult oral dose of doxycycline hyclate is 100 mg every twelve hours the first day, then 100 to 200 mg once a day; or 50 to 100 mg every twelve hours. Adverse reactions include anorexia, nausea, vomiting, diarrhea, and glossitis. Possible allergic reaction to dust if inhaled, ingested or in contact with skin.  
 ACUTE: Eye, skin and/or respiratory tract irritation.  
 CHRONIC: Possible hypersensitization.  
 PRECAUTIONS TO CONSIDER: Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Individuals with previous history of significant allergy (especially to antibiotics) and/or asthma should avoid potential exposure to this material. Individuals hypersensitive to one tetracycline or tetracycline derivative may be hypersensitive to other tetracyclines also. Material may be irritating to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown.  
 MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to the material  
 CHEMICAL LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN:  
 NATIONAL TOXICOLOGY PROGRAM: No  
 I.A.R.C. MONOGRAPHS: No  
 OSHA: No  
 OTHER: n/a  
 ACGIH TLV: n/a  
 OTHER EXPOSURE LIMIT(S) USED: n/a  
 OSHA PERMISSIBLE EXPOSURE LIMIT: Not established  
 OTHER EXPOSURE LIMIT USED: Not established  
 EMERGENCY AND FIRST AID PROCEDURES: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention.  
 1. INHALATION: May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.  
 2. EYES: May cause irritation. Flush with copious amounts of water.  
 3. SKIN: May cause irritation. Flush with copious amounts of water.  
 4. INGESTION: May cause irritation. Flush out mouth with water.

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SECTION 6 - SPECIAL PROTECTION INFORMATION  
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RESPIRATORY PROTECTION (SPECIFY TYPE): NIOSH approved  
respirator

VENTILATION: Adequate

LOCAL EXHAUST: Recommended

MECHANICAL (GENERAL): Recommended

OTHER: n/a

PROTECTIVE GLOVES: Rubber or vinyl

EYE PROTECTION: Safety goggles

OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Protect exposed  
skin. Appropriate laboratory apparel.

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SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES  
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PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE: Store in  
tight container as defined in the United States  
Pharmacopeia. This material should be handled and stored  
per label and other instructions to ensure product  
integrity.

OTHER PRECAUTIONS: Avoid contact with eyes, skin or  
clothing. Avoid breathing dust or mist. Use with adequate  
dust control. Wash thoroughly after handling. Wear fresh  
clothing daily. Wash contaminated clothing before reuse.  
Do not permit eating, drinking or smoking near material.

STEPS TO BE TAKEN IN CASE MATERIAL IS SPILLED OR RELEASED:  
Wear nuisance dust respirator and rubber or vinyl gloves.  
Vacuum or sweep up spillage. Avoid dust. Place spillage  
in appropriate container for waste disposal. Wash  
contaminated clothing before reuse.

WASTE DISPOSAL METHODS: Dispose of waste in accordance with  
all applicable Federal, State and local laws.

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COMPAS Code: 12360021