

Oxytetracycline Hydrochloride

sc-205785



The Power is Question

Material Safety Data Sheet

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Oxytetracycline Hydrochloride

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

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EMERGENCY:

ChemWatch
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SYNONYMS

C22-H24-N2-O9.HCl, "2-naphthacenicarboxamide, ", "4-(dimethylamino)-1, 4, 4A, 5, 5A, 6, 11, 12A-octahydro-3, 6, 10, 12, 12A-", "hexahydroxy-6-methyl-1, 11-dioxo-, monohydrochloride", "tetracycline antibiotic"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability:	1	
Toxicity:	2	
Body Contact:	2	
Reactivity:	1	
Chronic:	3	

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Possible risk of harm to the unborn child.
Irritating to eyes, respiratory system and skin.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.
- In a 13-week oral study with oxytetracycline, in mice and rats, no dose-related effects were observed on mortality, food consumption, macroscopic or histopathologic evaluation. In mice, a decrease in body weight gain was seen at 50,000 ppm. The NOAEL was 25,000 ppm. In male rats, mild fatty metamorphosis was observed in the liver of all treated animals. The NOAEL in rats was 50,000 ppm, equivalent to 3352 (males) mg/kg/day or 3494 (females) mg/kg/day.
- Tetracyclines produce nausea, abdominal pain and burning, vomiting, transitory yellowish-brown discoloration of the tongue, loss of appetite, and diarrhea. Large oral doses may produce liver and kidney damage.

EYE

- This material can cause eye irritation and damage in some persons.

SKIN

- This material can cause inflammation of the skin oncontact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
- Tetracyclines can cause yellow discoloration of the skin. Adverse effects can occur whether the drug is given orally or injected.

INHALED

- The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Results in experiments suggest that this material may cause disorders in the development of the embryo or fetus, even when no signs of poisoning show in the mother.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Skin sensitisation and/ or photosensitisation (allergic response after UV exposure have been demonstrated with clinical use of oxytetracycline.

In a 12-month study in dogs, a degenerating epithelium in the testicular tubules was observed in males fed diets containing 10,000 ppm (equivalent to 250 mg/kg/day) oxytetracycline hydrochloride. However, in a subsequent 24-month study in dogs, this effect was observed in control animals at a higher frequency than in treated animals and no adverse effects were reported at 250 mg/kg/day, the highest dose tested.

Effects on fertility (litter size) and embryo- or foetotoxicity were observed in rats at subcutaneous doses of oxytetracycline at 1000 mg/kg, in rabbits at intramuscular doses at 789 mg/kg, and in dogs at 643 mg/kg (no other details reported). In a rat teratology study, decreased ossification in the anterior extremities of foetuses and increased foetal resorptions were reported a 480 mg/kg/day; the NOAEL was 240 mg/kg/day. No increase in congenital effects was found in mice and rats treated with oxytetracycline at oral doses of 1500 and 2100 mg/kg on days 6-15 of gestation, respectively. In rabbits, oxytetracycline was administered intramuscularly at 41.5 mg/kg/day from day 10-28 of gestation. The number and percentage of partial and total resorptions were significantly increased; no effects on foetal body weight were observed. No

abnormalities were found at necroscopy.

In studies conducted by the US National Toxicological Program (NTP), no evidence of carcinogenicity was seen in mice at doses up to 1400 mg/kg/day. In rats, adrenal lesions in males and in the pituitary in females were observed at doses up to 2000 mg/kg/day. Based on these results the NTP was unable to classify for carcinogenicity..

Oxytetracycline was not mutagenic in microbial cells, but was weakly positive in in vitro mammalian cells. Overall, it was judged not to be genotoxic.

Repeated or prolonged exposures to tetracyclines can cause sore throat, hoarseness, a black hairy tongue, bulky loose stools, fat in the feces, inflammation of the mouth cavity, difficulty swallowing, damage to the anogenital area and ulcers of the esophagus. Deposits in the eye may cause abnormal pigmentation of the conjunctivae.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
oxytetracycline hydrochloride	2058-46-0	>95

Section 4 - FIRST AID MEASURES

SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to

maintain open airway and prevent aspiration.

EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

■ Treat symptomatically.

Tetracyclines are bound to plasma proteins and are widely distributed in the body tissues and fluids. The biological half-life is reported to be around 10-15 hours.

They are excreted in urine and in faeces.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available.
Lower Explosive Limit (%):	30-40 g/m3

EXTINGUISHING MEDIA

· Water spray or fog.

· Foam.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.

· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.

· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen chloride, phosgene, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

Dust Explosion Hazard Class 1

Dusts fall into one of three Kst* classes. Class 1 dusts; Kst 1-200 m3/sec; Class 2 dusts; 201-299 m3/sec.

Dusts with Minimum Ignition Energies (MIEs) ranging between 20 and 100 mJ may be sensitive to ignition. They require that:

· plant is grounded

· personal might also need to be grounded

· the use of high resistivity materials (such as plastics) should be restricted or avoided during handling or in packaging

The majority of ignition accidents occur within or below this range.

Maximum Explosion Risk: 7.5 bar.g

Maximum rate of pressure rise: 429 bar.s

Kst value: 116 bar.m/s

St Class: 1

Minimum Ignition energy: 100-300 mJ

Minimum dust cloud ignition temp: 480-500 C.

Limiting O₂ conc." 8.2-9.8% vol.

Powder Resistivity: ambient 1.3 x 10 exp 13

low 1.7 x 10 exp 13

Charge Relaxation: ambient 5.55 min. sec

low 29.23 min.sec

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

· Clean up waste regularly and abnormal spills immediately.

- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
 - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
 - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

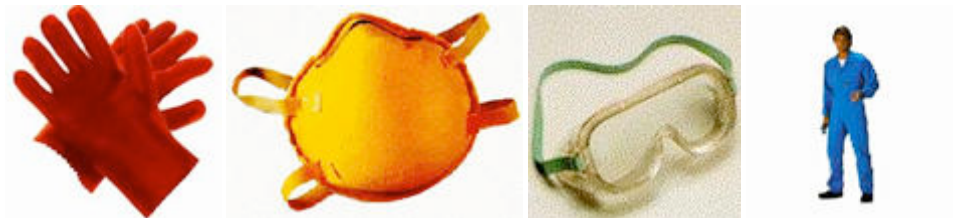
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- oxytetracycline hydrochloride: CAS:2058-46-0

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

- When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
 - frequency and duration of contact,
 - chemical resistance of glove material,
 - glove thickness and
 - dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.

- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
 - Contaminated gloves should be replaced.
- Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
 - Double gloving should be considered.
 - PVC gloves.
 - Protective shoe covers.
 - Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

- Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Assess operations based upon available dust explosion information to determine the suitability of preventative or protective systems as precautionary measures against possible dust explosions. If prevention is not possible, consider protection by use of containment, venting or suppression of dust handling equipment. Where explosion venting is considered to be the most appropriate method of protection, vent areas should preferably be calculated based on Kst rather than an St value. If nitrogen purging is considered as the protective system, it must operate with an oxygen level below the limiting oxygen concentration. The system should include an oxygen monitoring and shut-down facility in the event of excessive oxygen being detected.

The maximum surface temperature of enclosures potentially exposed to this material should be based on values obtained by taking 2/3 of the minimum ignition temperature (MIE) of the dust cloud. The effect of dust layers should be reviewed.

An isolated (insulated) human body can readily produce electrostatic discharges in excess of 50 mJ, but have been recorded up to 100 mJ.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	496.9
Melting Range (°F)	428- 433.4	Viscosity	Not Applicable
Boiling Range (°F)	Not available.	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	2.3-2.9
Decomposition Temp (°F)	>356	pH (as supplied)	Not applicable
Autoignition Temp (°F)	896	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available.
Lower Explosive Limit (%)	30-40 g/m3	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Pale yellow powder, soluble in water (1:2). No odour. Hygroscopic. Affected by light and moisture. Solutions in water become turbid on standing due to hydrolysis and consequent precipitation of oxytetracycline base.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

STORAGE INCOMPATIBILITY

- Protect from light.

Avoid reaction with oxidizing agents.
May darken in moist air when exposed to strong sunlight.
For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

OXYTETRACYCLINE HYDROCHLORIDE

TOXICITY AND IRRITATION

OXYTETRACYCLINE HYDROCHLORIDE:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Intarvenous (rat) LD50: 302 mg/kg *	Nil Reported
Subcutaneous (rt) LD50: 800 mg/kg *	
Oral (mouse) LD50: 6696 mg/kg	
Subcutaneous (mouse) LD50: 600 mg/kg *	

Intravenous (mouse) LD50: 100 mg/kg

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

Mammalian lymphocyte mutagen (in vivo)

Equivocal tumorigen by RTECS criteria

Reproductive effector in woman

* Pfizer

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
oxytetracycline hydrochloride	HIGH		LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

‡ Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

oxytetracycline hydrochloride (CAS: 2058-46-0) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)","US - California Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity","US - California Proposition 65 - Reproductive Toxicity","US - Maine Chemicals of High Concern List","US Toxic Substances Control Act (TSCA) - Inventory"

Section 16 - OTHER INFORMATION

ND

Substance CAS Suggested codes oxytetracycline hydrochloride 2058- 46- 0

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■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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