

1. Identification

Product identifier	Oxytetracycline		
Other means of identification			
Catalog number	1491004		
Chemical name	2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-, [4S-(4alpha, 4a alpha, 5alpha, 5a alpha, 6beta, 12a alpha)]-, dihydrate		
Synonym(s)	Hydroxytetracycline		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 2
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	Suspected of damaging fertility or the unborn child.
Precautionary statement	
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.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Not classified.
Other hazards which do not result in classification	None known.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Oxytetracycline	Hydroxytetracycline	6153-64-6	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Reproductive system effects.
Indication of immediate medical attention and special treatment needed	Tetracyclines are generally of a low order of toxicity. In most cases gastrointestinal decontamination will not be required. Treatment of overdose should be symptomatic and supportive and may include the following: 1. Immediately dilute with 4 to 8 ounces of water or milk. 2. For significant ingestion, administer activated charcoal as a slurry. 3. Antacids may be useful in managing gastric irritation. [Meditext 2008]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use Material

Type

Value

Oxytetracycline (CAS
6153-64-6)

TWA

0.5 mg/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Pale yellow to tan, crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	354.2 - 364.1 °F (179 - 184.5 °C) (decomposes) / 364.1 °F (184.5 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Very slightly soluble.
Partition coefficient (n-octanol/water)	-0.9
Auto-ignition temperature	1310 °F (710 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Tetracycline.
Molecular formula	C ₂₂ H ₂₄ N ₂ O ₉
Molecular weight	460.44 g/mol
pH in aqueous solution	4.5 (1% solution)
Solubility (other)	Freely soluble in 3 N hydrochloric acid and in alkaline solutions; sparingly soluble in alcohol; practically insoluble in chloroform.
Specific gravity	1.63 at 20 °C

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.

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.

Acute toxicity Based on available data, the classification criteria are not met.

Product	Species	Test Results
Oxytetracycline (CAS 6153-64-6)		
Acute Oral LD50	Mouse	2240 mg/kg
	Rat	4800 mg/kg

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.

Germ cell mutagenicity Due to lack of data the classification is not possible. Oxytetracycline hydrochloride was not mutagenic in Salmonella typhimurium strains TA100, TA1535, TA1537, or TA98 in the presence or absence of Aroclor 1254-induced male Sprague-Dawley rat or male Syrian hamster liver S9 when assayed according to the preincubation protocol. Oxytetracycline hydrochloride was mutagenic in L5178Y/TK+/- mouse lymphoma cells in the presence but not in the absence of Aroclor 1254-induced male rat liver S9. In cultured Chinese hamster ovary cells, oxytetracycline was weakly positive in inducing sister-chromatid exchanges both with and without Aroclor 1254-induced male Sprague-Dawley rat liver S9 but did not induce chromosomal aberrations.

Carcinogenicity Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Reproductive toxicity Suspected of damaging fertility or the unborn child. In humans, oxytetracycline has been associated with congenital abnormalities such as neural tube defects, cleft palate, and heart malformations when used during the second and third months of pregnancy when mothers received approximate total doses of oxytetracycline of 2.16 grams daily. Staining of teeth and other effects on the tooth enamel may occur in offspring of mothers treated with oxytetracycline during the second or third trimester of pregnancy at an average dose of 1 gram daily for 15 days. Studies in dogs and in rabbits given this material resulted in increased frequencies of skeletal and other malformations in the offspring; however, studies in mice showed no increase in congenital defects.

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity Very toxic to aquatic life.

Product		Species	Test Results
Oxytetracycline (CAS 6153-64-6)			
Aquatic			
Crustacea	EC50	Whiteleg shrimp (Penaeus vannamei)	0.0611 mg/l, 48 hours
Fish	LC50	Striped bass (Morone saxatilis)	75 mg/l, 96 hours
Acute			
Fish	LC50	Lake trout (Salmo trutta lacustris)	< 200 mg/l, 96 hours
		Striped bass (Morone saxatilis)	75 mg/l, 96 hours

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose of in accordance with local regulations.
Hazardous waste code	Not regulated.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN3077
UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Packaging exceptions	155
Packaging non bulk	213
Packaging bulk	240

IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Oxytetracycline)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

DOT; IATA



General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-29-2008
Revision date 09-08-2015
Version # 03
Further information Not available.

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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.