

SAFETY DATA SHEET

1. Identification

Product identifier Chlortetracycline Hydrochloride

Other means of identification

Catalog number 1129007 CAS number 64-72-2

Chemical name 2-Naphthacenecarboxamide, 7-chloro-4(dimethylamino-1,4,4a,5,5a,6,11,12a-octahydro-

3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, monohydrochloride [4S-(4alpha, 4a alpha, 5a

alpha, 6beta, 12a alpha)]-

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 nameU. S. PharmacopeiaAddress12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

Telephone RS Technical Services

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US &

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Skin corrosion/irritation Category 2

Serious eye damage/eye irritation Category 2A Reproductive toxicity Category 2

301-816-8129

1-800-424-9300

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Causes skin irritation. Causes serious eye irritation. 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. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye

protection/face protection.

Response If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take

off contaminated clothing and wash before reuse. 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. 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)

None known.

Supplemental information Pharmacologically active material.

Material name: Chlortetracycline Hydrochloride

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%	
Chlortetracycline Hydrochloride		64-72-2	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. Remove contaminated clothing. Get medical attention if irritation

develops and persists.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. 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

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Treatment of tetracycline overdose may include the following: Immediately dilute with water or milk. Gastrointestinal decontamination is generally not required due to low order toxicity. Administer activated charcoal as a slurry. For gastrointestinal irritation, administer antacids. For mild/moderate allergic reaction, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reactions, treat with aggressive airway management, antihistamines, epinephrine, corticosteroids, ECG monitoring, and IV fluids. [Meditext 2006]

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

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

Specific methods

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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

Occupational exposure limits No exposure limits noted for ingredient(s). **Biological limit values**

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

Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of Other

skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face Respiratory protection

respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task

and the level of existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder.

Color Yellow Odorless. Odor **Odor threshold** Not available. Not available. рΗ

334.4 - 336.2 °F (168 - 169 °C) (decomposes above 210 ° C) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Flammability limit - upper

Not available.

Not available.

Not available. Explosive limit - lower (%)

Explosive limit - upper (%) Not available.

< 0.0000001 kPa at 25 °C Vapor pressure

Vapor density 17.8

Not available. Relative density

Solubility(ies)

Solubility (water) Sparingly soluble.

Acetone: Practically insoluble Solubility (other)

Alkali hydroxides: Soluble Carbonates: Soluble

Chloroform: Practically insoluble Dioxane: Practically insoluble Ether: Practically insoluble

Auto-ignition temperature Not available. Not available. **Decomposition temperature** Not available **Viscosity**

Other information

Chemical family Tetracycline.

C22H23CIN2O8.CIH Molecular formula

Molecular weight 515.34

2.3 to 3.3 Solution: 1% pH in aqueous solution

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Contact with incompatible materials. Conditions to avoid

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. Cl-. NOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact Causes skin irritation.

Eye contact Causes serious eye irritation.

Knowledge about health hazard is incomplete. Ingestion

Symptoms related to the

physical, chemical, and

toxicological characteristics Tetracyclines: Gastrointestinal disturbances. Irritant effects. Dizziness. Unsteadiness. Bone or

tooth discoloration.

Information on toxicological effects

Acute toxicity

Product Test Results Species

Chlortetracycline Hydrochloride (CAS 64-72-2)

Oral

LD50 Mouse 2314 mg/kg Rat 10300 mg/kg

Causes skin irritation. Skin corrosion/irritation

Serious eye damage/eye

irritation

Causes serious eye irritation.

Local effects

Eye irritation, 1% solution Result: Mild irritation Species: Rabbit

Respiratory or skin sensitization

Knowledge about health hazard is incomplete. Respiratory sensitization Knowledge about health hazard is incomplete. Skin sensitization Knowledge about mutagenicity is incomplete. Germ cell mutagenicity

Mutagenicity

Ames test, (E. coli and S. typhimurium)

Result: Negative.

Mutagenicity, Chromosome aberration test

Result: Negative. Species: Rat

Mutagenicity, HGPRT assay (Chinese hamster ovary cells)

Result: Negative.

Mutagenicity, Unscheduled DNA synthesis (rat hepatocytes)

Result: Negative.

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

> 5000 mg/kg/day Two year chronic carcinogenicity study Result: Fatty livers and testicular atrophy but no carcinogenic

effects Species: Rat

Material name: Chlortetracycline Hydrochloride 1129007 Version #: 03 Revision date: 01-05-2018 Issue date: 10-24-2006

IARC Monographs. Overall Evaluation of Carcinogenicity

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Suspected of damaging fertility or the unborn child.

Oral 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 acid infiltration of the liver, leading to damage or failure, may

occur in pregnant women.

Reproductivity

1125 mg/kg Reproductivity, (subcutaneous)

Result: Reduced weight gain and viability in offspring.

Species: Mouse

Specific target organ toxicity single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

Pharmacologically active material. Occupational exposure may cause physiological effects. **Further information**

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

No data is available on the degradability of this product. Persistence and degradability

Bioaccumulative potential No data available. No data available. Mobility in soil

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

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 in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

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 Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and

the IBC Code

General information

Not applicable.

It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Immediate Hazard - Yes **Hazard categories**

> Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Australia

Not regulated.

Inventory name

US state regulations WARNING: This product contains a chemical known to the State of California to cause birth

Australian Inventory of Chemical Substances (AICS)

defects or other reproductive harm.

International Inventories

Country(s) or region

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)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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 10-24-2006 **Revision date** 01-05-2018

Version # 03

United States & Puerto Rico

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Toxic Substances Control Act (TSCA) Inventory

human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained

herein.

On inventory (yes/no)*

Yes

Nο