


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	TETRACYCLINE HYDROCHLORIDE, USP
PRODUCT CODE	0053
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Skin Irritation (Category 2) Eye Irritation (Category 2A) Toxic to Reproduction (Effects on or via lactation) Toxic to Reproduction (Category 1A)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Causes skin irritation. Causes serious eye irritation. May cause harm to breast-fed children. May damage fertility or the unborn child. Exposure may produce an allergic reaction. May cause respiratory irritation.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S)
Prevention

Obtain, read and follow all special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Wear protective gloves, protective clothing, eye and face protection and hearing protection.
 Do not breathe dusts or mists.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling. Do not touch eyes.
 Do not eat, drink or smoke when using this product.
 Avoid breathing dust, fume, gas, mist, vapors, spray.
 In case of inadequate ventilation wear respiratory protection.

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 help
 IF ON SKIN: Wash with plenty of water. If skin irritation occurs, get medical help. Take off contaminated clothing and wash it before reuse.
 IF EXPOSED OR CONCERNED: Get medical advice.

Storage

Store locked up.

Disposal

Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION
Health Hazard

2

Flammability

0

Reactivity

0

Personal Protection

E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
CHEMICAL NAME

(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-naphthacene-carboxamide monohydrochloride.

BOTANICAL NAME

Not applicable

SYNONYM

Not applicable

CHEMICAL FORMULA

C₂₂H₂₄N₂O₈.HCl

CHEMICAL FAMILY

Tetracycline

CAS NUMBER

64-75-5

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

480.8985

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
TETRACYCLINE HCl	64-75-5	200-593-8	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 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 15 minutes. 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.

**MEDICAL ATTENTION AND
SPECIAL TREATMENT**

Get emergency medical help.

**SYMPTOMS CAUSED BY
EXPOSURE**

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING 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.

**SUITABLE & UNSUITABLE
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.

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, 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.

**REFERENCE TO OTHER
SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 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. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE
STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: TETRACYCLINE HCl CAS #: 64-75-5

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

**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. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING
CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

Pharmacologically active material. Occupational exposure may cause physiological effects.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
**PHYSICAL
STATE**

Solid

DESCRIPTION

Yellow odorless crystalline powder. Is moderately hygroscopic. Is stable in air, but exposure to strong sunlight in moist air causes it to darken.

SOLUBILITY

Soluble in water and in solutions of alkali hydroxides and carbonates; slightly soluble in alcohol; practically insoluble in chloroform and in ether.

ODOR	Odorless				
FLAMMABILITY	May be combustibile at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	(214 - 223)°C, (417.2-433.4)°F
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(214 - 223)°C, (417.2-433.4)°F (Decomposes)
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	1.8 - 2.8 (1%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.72	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.000001 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established.
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	Strong bases. Reducing agents. Strong oxidizing agents.
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. Hygroscopic - Avoid exposure to moisture.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 6443 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Causes skin irritation. pH: 1.8 - 2.8 (1%)
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes serious eye irritation. pH: 1.8 - 2.8 (1%)

RESPIRATORY 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.

SKIN SENSITIZATION

Due to lack of data, the classification is not possible.

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.
Genotoxicity tests have shown mixed results. Data from germ cell mutagenicity tests were not found.

CARCINOGENICITY

OSHA TETRACYCLINE HYDROCHLORIDE is not listed.

NTP TETRACYCLINE HYDROCHLORIDE is not listed.

IARC TETRACYCLINE HYDROCHLORIDE is not evaluated.

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

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
Carcinogenicity study: Rat: 12500 ppm No evidence of carcinogenicity.
Carcinogenicity study: Mouse: 25000 ppm: No evidence of carcinogenicity.

REPRODUCTIVE TOXICITY

Suspected of damaging fertility or the unborn child.
Tetracyclines: Use of tetracyclines during the last half of pregnancy may cause permanent discoloration of the teeth, complete development or lack of enamel, and inhibition of skeletal growth in the fetus.
Tetracyclines administered early in pregnancy have been found to cause harm to the embryo, including congenital cataracts. 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

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

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

**SIGNS AND SYMPTOMS OF
EXPOSURE**
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Tetracyclines: Superinfections. Antibiotic-associated colitis. Liver toxicity.

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.

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.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: *Salvelinus namaycush*: (mg/L): 186.9 - 258.9

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND
DEGRADABILITY**

Potentially biodegradable.

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Soluble in water.

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
HAZCHEM

Not applicable

EU
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not Listed

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
TETRACYCLINE HCl 64-75-5	N/L	X	N/L	N/L	N/L	X	X	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
TETRACYCLINE HCl 64-75-5	N/L	Listed as Schedule 4*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
TETRACYCLINE HCl 64-75-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

NOTES

*Tetracycline is listed.

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

10/2023

SUPERSEDES

04/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.