


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	DOXYCYCLINE HYCLATE USP
PRODUCT CODE	0434
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	Acute Toxicity - Oral (Category 4) Toxic to Reproduction (Category 1A), Effects on or via lactation Skin Irritation (Category 2) Eye Irritation (Category 2A) Sensitization - Skin (Category 1) Specific Target Organ Toxicity - Single Exposure (Category 3) : Respiratory Acute Aquatic Toxicity (Category 2)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Harmful if swallowed. May damage fertility or the unborn child. May cause harm to breast-fed children. Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction. May cause respiratory irritation. Toxic to aquatic life.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable

PRECAUTIONARY STATEMENT(S)

Prevention	Wash thoroughly after handling. Do not touch eyes. Do not eat, drink or smoke when using this product. 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. Contaminated work clothing should not be allowed out of the workplace. Avoid breathing dust/fume/gas/mist/ vapors/spray. Use only outdoors or in a well-ventilated area. Avoid release to the environment.
Response	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor 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 advice/attention. Take off contaminated clothing and wash it before reuse IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor if you feel unwell.
Storage	Store in a well ventilated place. Keep container tightly closed. 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	X

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	4-(Dimethylamino)-1, 4, 4a, 5, 5a, 6, 11, 12a-octahydro-3, 5, 10, 12, 12a-pentahydroxy-6-methyl-1, 11-dioxo-2-naphthacene-carboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate.
BOTANICAL NAME	Not applicable
SYNONYM	Not applicable
CHEMICAL FORMULA	$(C_{22}H_{24}N_2O_8 \cdot HCl)_2 \cdot C_2H_6O \cdot H_2O$
CHEMICAL FAMILY	Tetracycline derivative
CAS NUMBER	24390-14-5
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	1025.88

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
DOXYCYCLINE HYCLATE (Monohydrate)	24390-14-5	657-194-0	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, light and moisture. Short term excursions such as during shipping, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: DOXYCYCLINE HYCLATE (Monohydrate) CAS #: 24390-14-5

	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

 USP: ELV: Industrial: TWA: 250 micrograms/m³
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

Yellow crystalline powder. Is hygroscopic.

SOLUBILITY

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

ODOR

Not available

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

900 °C, 1652 °F

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

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

206 - 209 °C (403- 408 °F)

PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	2-3 (1%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 1 mm Hg	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 oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight, light and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 1700 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Causes skin irritation.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes serious eye irritation.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	May cause an allergic skin reaction.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	OSHA DOXYCYCLINE HYCLATE is not listed. NTP DOXYCYCLINE HYCLATE is not listed. IARC DOXYCYCLINE HYCLATE is not evaluated. California Proposition 65 This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: DOXYCYCLINE HYCLATE.
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of data the classification is not possible.
REPRODUCTIVE TOXICITY	Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

May cause respiratory irritation.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

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

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:

Not available

Symptoms related to the physical, chemical, and toxicological characteristics:

Tetracyclines: Gastrointestinal disturbances. Irritant effects. Dizziness. Unsteadiness. Bone or tooth discoloration.

POTENTIAL HEALTH EFFECTS
Inhalation

May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion

Harmful if swallowed.

Skin

May be harmful if absorbed through skin. Causes skin irritation. May cause an allergic skin reaction.

Eyes

Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

DOXYCYCLINE (Monohydrate):

EC50: 48 Hr: Crustacea: (mg/L): 2.89*

LC50: 96 Hr: Fish: (mg/L): 27.42*

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): 3.37*

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Soluble in water

OTHER ADVERSE EFFECTS

May be harmful to aquatic life

This product is not intended to be released into the environment

NOTES

* Danish QSAR database

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 Part 372.65	EPA 40 CFR Part 365		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
DOXYCYCLINE HYCLATE 24390-14-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
DOXYCYCLINE HYCLATE 24390-14-5	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
DOXYCYCLINE HYCLATE 24390-14-5	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

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

12/2025

SUPERSEDES

01/2023

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.