

SAFETY DATA SHEETS

This SDS packet was issued with item:

078908342

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078588423 078588431 078596265 078596273 078656750 078697137 078907569 078907570 078907599 078908343
078910054 078910190


The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078588449

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 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 8300 Esters Blvd., Suite 940, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 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
USES	Antibacterial

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4); Specific Target Organ Toxicity - Single Exposure (Category 3); Eye Irritation (Category 2A); Skin Irritation (Category 2); Toxic to Reproduction (Category 1B)		
PICTOGRAM			
SIGNAL WORD	Danger		
HAZARD STATEMENT(S)	Harmful if swallowed. May cause respiratory irritation. Causes serious eye irritation. Causes skin irritation. May damage fertility or the unborn child.		
AUSTRALIA-ONLY HAZARDS	Not Applicable		
PRECAUTIONARY STATEMENT(S)	Prevention	Wash thoroughly after handling; Do not eat, drink or smoke when using this product. 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 swallowed: Immediately call a poison center or medical professional; Rinse mouth. If exposed or concerned: Get medical advice/attention. 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 on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.	
	Storage	Store locked up.	
	Disposal	Dispose of contents and/or container in accordance with local regulations.	
HMIS CLASSIFICATION	Health Hazard	1	Flammability 1
	Reactivity	0	Personal Protection E

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-naphthacenecarboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate.		
BOTANICAL NAME	Not applicable		
SYNONYM	Not applicable		
CHEMICAL FORMULA	(C ₂₂ H ₂₄ N ₂ O ₈ •HCl) ₂ •C ₂ H ₆ O•H ₂ O		
CAS NUMBER	24390-14-5		
ALTERNATE CAS NUMBER	Not applicable		
MOLECULAR WEIGHT	1025.86		
COMPOSITION	CHEMICAL NAME		
	DOXYCYCLINE HYCLATE	CAS NUMBER	% BY WEIGHT
		24390-14-5	100

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.
SYMPTOMS AND EFFECTS	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.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.

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.

STORAGE CONDITIONS

Preserve in tight containers, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name	CAS	OSHA PEL			AIHA WEEL		Safe Work Australia HSIS	
		TWA	Ceiling	Skin Designation	8hr TWA	Ceiling	TWA	STEL
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

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits

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.

SPECIFIC ENGINEERING CONTROLS

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Yellow crystalline powder. Is hygroscopic.

SOLUBILITY

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

As per EP: Freely soluble in water and in methanol, sparingly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and carbonates.

ODOR

Not available

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD

Not available

PH

2-3

MELTING POINT

~201 °C, ~393.8 °F

BOILING POINT

Not available

FREEZING POINT

Not available

FLASH POINT

Not available

SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	Not available
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	LOG P (OCTANOL-WATER)	Not available
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	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 and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: 1700 mg/kg
SKIN CORROSION/IRRITATION	Not available
SERIOUS EYE DAMAGE/EYE IRRITATION	Not available
RESPIRATORY OR SKIN SENSITIZATION	Not available
GERM CELL MUTAGENICITY	Not available
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.
REPRODUCTIVE TOXICITY	Adverse effects on fertility and reproductive performance were observed in male rats administered oral doxycycline hyclate at doses as low as 50 mg/kg/day. There were no effects on the fertility of female rats administered oral doxycycline at doses up to 250 mg/kg/day. There was no evidence of an increase in birth defects in the offspring of pregnant rats, rabbits, or mice administered doxycycline at doses more than 100 times those used clinically, or pregnant rats, rabbits, or monkeys administered doxycycline at doses 2 - 17 times the maximum human dose. Fetal toxicity occurred in pregnant mice fed 2.5 - 10 mg/gram doxycycline in their feed.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Inhalation - May cause respiratory irritation.								
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Not available								
ASPIRATION HAZARDS	Not available								
SIGNS AND SYMPTOMS OF EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.								
POTENTIAL HEALTH EFFECTS	<table> <tr> <td>Inhalation</td><td>May be harmful if inhaled. May cause upper respiratory tract irritation.</td></tr> <tr> <td>Ingestion</td><td>Harmful if swallowed.</td></tr> <tr> <td>Skin</td><td>May be harmful if absorbed through skin. May cause skin irritation</td></tr> <tr> <td>Eyes</td><td>May cause eye irritation.</td></tr> </table>	Inhalation	May be harmful if inhaled. May cause upper respiratory tract irritation.	Ingestion	Harmful if swallowed.	Skin	May be harmful if absorbed through skin. May cause skin irritation	Eyes	May cause eye irritation.
Inhalation	May be harmful if inhaled. May cause upper respiratory tract irritation.								
Ingestion	Harmful if swallowed.								
Skin	May be harmful if absorbed through skin. May cause skin irritation								
Eyes	May cause eye irritation.								
NOTES	May cause sensitivity of the skin to sunlight, dizziness, unsteadiness, joint pain, cramps or burning of the stomach, diarrhea, nausea or vomiting, itching of the rectal or genital area, sore mouth or tongue, discoloured tongue; possible allergic reaction to material.								

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Not available
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
HAZCHEM	Not Applicable

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Right-to-know			California Prop 65
			Appendix A	Appendix B	Pennsylvania	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
DOXYCYCLINE HYCLATE 24390-14-5	N/L	N/L	N/L

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH/MSHA** – National Institute for Occupational Safety and Health/Mine Safety and Health Administration;

LAST REVISION

7/2014

SUPERSEDES

12/2013

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.