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
   661 Route 3, Unit C, Plattsburgh, NY, 12901
   3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
   6641 N. Belt Line Road, Suite 130, 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:
   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.

AUSTRALIA-ONLY HAZARDS:
   Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S):
   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.
      Do not breathe dusts or mists.
      Avoid contact during pregnancy/while nursing.
      Wash thoroughly after handling.
      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.
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
(4S,4aS,5aS,6S,12aS)-(4-(Dimethylamino)-1,4,4a,5,5a,6,11,12-tetrahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride.

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable

CHEMICAL FORMULA
C_{22}H_{24}N_{2}O_{8}.HCl

CAS NUMBER
64-75-5

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
480.9885

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETRACYCLINE HCl</td>
<td>64-75-5</td>
<td>100</td>
</tr>
</tbody>
</table>

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.

NOTES
Chemical family: Tetracycline.

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.
**SAFETY DATA SHEET**

**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.

**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 unlabelled 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. Preserve in tight, light-resistant containers.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

**Chemical Name:** TETRACYCLINE HYDROCHLORIDE  
**CAS #:** 64-75-5

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

N/L = Not Listed

**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.
**SPECIFIC ENGINEERING CONTROLS**
Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

**NOTES**
Pharmacologically active material. Occupational exposure may cause physiological effects.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th><strong>PHYSICAL STATE</strong></th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>Yellow odorless crystalline powder. Is moderately hygroscopic. Is stable in air, but exposure to strong sunlight in moist air causes it to darken.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Soluble in water and in solutions of alkali hydroxides and carbonates; slightly soluble in alcohol; practically insoluble in chloroform and in ether.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>PH</strong></td>
<td>1.8 - 2.8 (1%)</td>
</tr>
<tr>
<td><strong>MELTING POINT</strong></td>
<td>(214 - 223)°C, (417.2-433.4)°F (Decomposes)</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>FREEZING POINT</strong></td>
<td>(214 - 223)°C, (417.2-433.4)°F</td>
</tr>
<tr>
<td><strong>FLASH POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
<td>0.72</td>
</tr>
<tr>
<td><strong>EVAPORATION RATE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>EXPLOSIVE LIMIT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOUR PRESSURE</strong></td>
<td>&lt; 0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td><strong>RELATIVE DENSITY</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>WATER = 1</strong></td>
<td>log P (OCTANOL-WATER)</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>(214 - 223)°C, (417.2-433.4)°F</td>
</tr>
<tr>
<td><strong>VISCOSITY</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

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

## SECTION 10: STABILITY AND REACTIVITY

| **REA CTIVITY** | Not established. |
| **STABILITY** | Stable under recommended storage conditions. |
| **MATERIALS TO AVOID** | 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. |
## 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

### PH

- **Skin Corrosion/Irritation**: pH: 1.8 - 2.8 (1%)
- **Serious Eye Damage/Eye Irritation**: pH: 1.8 - 2.8 (1%)

### RESPIRATORY OR SKIN 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.

### 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 65**: 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

The 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 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. Pharmacologically active material. Occupational exposure may cause physiological effects. Symptoms related to the physical, chemical, and toxicological characteristics:


- **Delayed and immediate effects of exposure:**

- **Cross sensitivity:**
  - Persons sensitive to any of the tetracyclines may be sensitive to this material also.
### POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>May be harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. Causes skin irritation.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes serious eye irritation.</td>
</tr>
</tbody>
</table>

### SECTION 12: ECOLOGICAL INFORMATION

#### TOXICITY
- 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.
- Not available

#### BIOACCUMULATIVE POTENTIAL
- Soluble in water.
- Not available

#### MOBILITY IN SOIL
- Not available

#### OTHER ADVERSE EFFECTS
- 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.

### 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

#### ENVIRONMENTAL HAZARDS
- Not available

#### SPECIAL SHIPPING INFORMATION
- Not applicable

### SECTION 15: REGULATORY INFORMATION
**SAFETY DATA SHEET**

**Chemical Name & CAS**

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TETRACYCLINE HCl 64-75-5</td>
<td>N/L</td>
<td>X</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETRACYCLINE HCl 64-75-5</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
</tr>
</tbody>
</table>

**NOTES**

*Tetracycline is listed.

**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 – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL – Recommended Exposure Limit

**LAST REVISION**
11/2018

**SUPERSEDES**
11/2015

**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.