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, anti-amoebic, anti-rickettsial.

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)
Specific Target Organ Toxicity - Single Exposure (Category 3)

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

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 advice/attention.
IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
IF EXPOSED OR CONCERNED: Get medical advice/attention.

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-naphthacencarboxamide monohydrochloride.

BOTANICAL NAME
Not applicable

SYNONYM
Not applicable

CHEMICAL FORMULA
C₂₂H₂₄N₂O₈.HCl

CAS NUMBER
64-75-5

ALTERNATE CAS NUMBER
Not applicable

MOLECULAR WEIGHT
480.8985

COMPOSITION
<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETRACYCLINE HYDROCHLORIDE</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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. 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.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<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>Not available</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>VAPOR DENSITY (AIR = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR PRESSURE</strong></td>
<td>&lt; 0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REACTIVITY</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>STABILITY</strong></td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td><strong>MATERIALS TO AVOID</strong></td>
<td>Strong oxidants, solutions of metal cations, strong bases.</td>
</tr>
<tr>
<td><strong>HAZARDOUS DECOMPOSITION PRODUCTS</strong></td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, chloride and other gases may occur</td>
</tr>
<tr>
<td><strong>HAZARDOUS POLYMERIZATION</strong></td>
<td>Will not occur</td>
</tr>
<tr>
<td><strong>POSSIBILITY OF HAZARDOUS REACTION</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>CONDITIONS TO AVOID</strong></td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

Last Revision: 11/2015
SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 6443
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

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

Genotoxicity tests have shown mixed results.

Data from germ cell mutagenicity tests were not found.

Due to lack of data the classification is not possible.

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

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

Due to lack of data the classification is not possible.
SAFETY DATA SHEET

SIGN AND SYMPTOMS OF EXPOSURE
Not expected to present a significant hazard under anticipated conditions of normal use. May cause nausea, vomiting, diarrhoea, oesophageal ulceration, glossitis, stomatitis, dysphagia; oral candidiasis, vulvovaginitis, pruritus ani, renal dysfunction, increased liver enzymes, hepatotoxicity, permanent discoloration of the teeth and enamel hypoplasia; nail discoloration, onycholysis, abnormal pigmentation of the skin, conjunctiva, oral mucosa, tongue and internal organs; intracranial hypertension with headache, dizziness, tinnitus, visual disturbances, papilloedema; muscle weakness; rashes, fixed drug eruptions, exfoliative dermatitis, toxic epidermal necrolysis, drug fever, pericarditis, angioedema, urticarial, asthma; thrombophlebitis, agranulocytosis, aplastic anaemia, haemolytic anaemia, eosinophilia, neutropenia, thrombocytopenia, hypothyroidism, Fanconi-type syndrome. 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. Delayed and immediate effects of exposure: Tetracyclines: Superinfections. Antibiotic-associated colitis. Liver toxicity. 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

<table>
<thead>
<tr>
<th>Route of Exposure</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: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): 186.9 - 258.9
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Potentially biodegradable.

BIOACCUMULATIVE POTENTIAL
Not available

MOBILITY IN SOIL
Soluble in water.

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
SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>TETRACYCLINE HYDROCHLORIDE 64-75-5</td>
<td>N/L</td>
<td>X</td>
<td>N/L</td>
<td>N/L</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></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 HYDROCHLORIDE 64-75-5</td>
<td>Not Listed</td>
<td>Listed as Schedule 4*</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

*Tetracycline is listed.

NOTES

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
11/2015

SUPERSEDES
09/2013
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.