SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: CLINDAMYCIN HYDROCHLORIDE, USP
PRODUCT CODE: 0005
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
- 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 5)
- Eye Irritation (Category 2A)
- Sensitization - Skin (Category 1B)

PICTOGRAM

SIGNAL WORD
Warning

HAZARD STATEMENT(S)
- May cause an allergic reaction.
- May be harmful if swallowed.
- Causes serious eye irritation.
- Repeated exposure may cause skin dryness or cracking.

AUSTRALIA-ONLY HAZARDS

PRECAUTIONARY STATEMENT(S)
Prevention
- Wash thoroughly after handling.
- Wear eye and face protection.
- Avoid breathing dust, fume, gas, mist, vapors, spray.
- Contaminated work clothing must not be allowed out of the workplace.
- Wear protective gloves.

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: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Storage
- Not applicable.

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

HMIS CLASSIFICATION
- Health Hazard: 1
- Flammability: 0
- Reactivity: 0
- Personal Protection: D

Last Revision: 11/2018
SAFETY DATA SHEET

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-D-galacto-octopyranoside monohydrochloride</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOTANICAL NAME</td>
<td></td>
</tr>
<tr>
<td>SYNONYM</td>
<td>7-chloro-7-deoxylincomycin hydrochloride; Cleocin hydrochloride; Clindimycin hydrochloride</td>
</tr>
<tr>
<td>CHEMICAL FORMULA</td>
<td>C₁₈H₃₃ClN₂O₅S.HCl</td>
</tr>
<tr>
<td>CAS NUMBER</td>
<td>21462-39-5</td>
</tr>
<tr>
<td>ALTERNATE CAS NUMBER</td>
<td></td>
</tr>
<tr>
<td>MOLECULAR WEIGHT</td>
<td>461.4476</td>
</tr>
<tr>
<td>COMPOSITION</td>
<td></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: Glycoside (lincosamide) antibiotic.
- Chlorinated derivative of lincomycin. It is a mainly bacteriostatic drug.

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
- 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, 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.
SAFETY DATA SHEET

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. Store below 30°C (86°F), relative humidity not exceeding 75%. Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CLINDAMYCIN HYDROCHLORIDE (Anhydrous) CAS #: 21462-39-5

<table>
<thead>
<tr>
<th>Chemical</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. Fumehood, eye wash station, and safety shower.

NOTES

USP: ELV: Industrial: TWA: 0.1 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White or practically white, crystalline powder. Is odorless or has a faint mercaptan-like odor. Is stable in presence of air and light.

SOLUBILITY

Freely soluble in water, in dimethylformamide, and in methanol; soluble in alcohol; practically insoluble in acetone.
### SAFETY DATA SHEET

**ODOR**
Odorless or has a faint mercaptan-like odor

**FLAMMABILITY**
May be combustible at high temperature

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>3 - 5.5 (10%)</td>
</tr>
<tr>
<td>Melting Point</td>
<td>(141 - 143)°C, (285.8 - 289.4)°F</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Decomposes</td>
</tr>
<tr>
<td>Freezing Point</td>
<td>(141 - 143)°C, (285.8 - 289.4)°F</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive Limit</td>
<td>Not available</td>
</tr>
<tr>
<td>Upper Flammable/Explosive Limit(s)</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Flammable/Explosive Limit(s)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapour Density (Air = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Relative Density (Water = 1)</td>
<td>Not available</td>
</tr>
<tr>
<td>Log P (Octanol-Water)</td>
<td>1.015 (20°C)</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Viscosity</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

**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: (mg/kg): 2193
- Dermal: Rabbit LD50: (mg/kg): Not available
- Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**
Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE IRRITATION**
Causes serious eye irritation (pH 3 - 5.5)

**RESPIRATORY OR SKIN SENSITIZATION**
Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Rashes and urticaria occur in up to 10% of patients, erythema multiforme, Stevens-Johnson syndrome, exfoliative and vesiculobullos dermatitis have been reported rarely and a few cases of anaphylaxis have occurred.
SAFETY DATA SHEET

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

CARCINOGENICITY

<table>
<thead>
<tr>
<th>Agency</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA</td>
<td>CLINDAMYCIN HYDROCHLORIDE (Anhydrous) is not listed.</td>
</tr>
<tr>
<td>NTP</td>
<td>CLINDAMYCIN HYDROCHLORIDE (Anhydrous) is not listed.</td>
</tr>
<tr>
<td>IARC</td>
<td>CLINDAMYCIN HYDROCHLORIDE (Anhydrous) is not evaluated.</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td>
</tr>
</tbody>
</table>

ADDITIONAL CARCINOGENICITY INFORMATION

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met. Although it is unlikely that a breast-fed infant could absorb significant amounts, caution should be exercised when clindamycin is given during breast feeding. Reproductivity and development studies: Rat: 250 mg/kg/day administered subcutaneously: no-observed-adverse-effect-level Fertility study: Rat: 300 mg/kg/day administered orally: no observed adverse effect level Reproductivity and development studies: Rodent: 600 mg/kg/day administered orally: no observed adverse effect level

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

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. Significant nephrotoxicity and/or ototoxicity.

SIGNS AND SYMPTOMS OF EXPOSURE

Symptoms related to the physical, chemical, and toxicological characteristics: Nausea, Vomiting, Diarrhea, Abdominal pain, Bitter or metallic taste, Skin rash, Fever, Sore throat, Sore mouth or tongue, Bleeding or bruising, Ringing in ears, Vertigo.

Delayed and immediate effects of exposure: Superinfections, Pseudomembranous colitis, Neutropenia, Thrombocytopenia.

Cross sensitivity: Persons sensitive to lincomycin or doxorubicin may be sensitive to this material also.

Medical conditions aggravated by exposure: Colitis, Gastrointestinal disease, Liver impairment, History of significant allergy.

POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>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. May cause skin irritation. May cause an allergic reaction.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation.</td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50: 48 Hr: Crustacea</td>
<td>(mg/L): Not available</td>
</tr>
<tr>
<td>LC50: 96 Hr: Fish</td>
<td>(mg/L): Not available</td>
</tr>
<tr>
<td>EC50: 72 or 96 Hr: Algae (or other aqua plants)</td>
<td>(mg/L): Not available</td>
</tr>
</tbody>
</table>

PERSISTENCE AND DEGRADABILITY

The product is biodegradable.

BIOACCUMULATIVE POTENTIAL

Log Pow: 1.015 (20°C)

MOBILITY IN SOIL

Freely 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

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>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINDAMYCIN HYDROCHLORIDE (Anhydrous) 21462-39-5</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</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>CLINDAMYCIN HYDROCHLORIDE (Anhydrous) 21462-39-5</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
</tr>
</tbody>
</table>

NOTES

*Clindamycin 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.