SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: CLINDAMYCIN PHOSPHATE, USP
PRODUCT CODE: 0006
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 4)
- Eye Irritation (Category 2A)
- Sensitization - Skin (Category 1B)
PICTOGRAM:
- Warning

HAZARD STATEMENT(S):
- Harmful if swallowed.
- Causes serious eye irritation.
- May cause an allergic reaction.

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

PRECAUTIONARY STATEMENT(S):

Prevention:
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Avoid breathing dust, fume, gas, mist, vapors, and spray.
- Wear eye and face protection.
- Wear protective gloves.
- Contaminated work clothing must not be allowed out of the workplace.

Response:
- IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
- 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.
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| CHEMICAL NAME | L-threo-α-D-galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-\[[(1-methyl-4-propyl-2-pyrolidinyl)carbonyl]amino]-1-thio-, 2-(dihydrogen phosphate), (2S-trans)- |
| BOTANICAL NAME | Not applicable |
| SYNONYM | 7(S)-Chloro-7-deoxylincomycin 2-phosphate; Clindamycin 2-dihydrogen phosphate |
| CHEMICAL FORMULA | C₁₈H₃₄ClN₂O₈P |
| CAS NUMBER | 24729-96-2 |
| MOLECULAR WEIGHT | 504.97 |

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLINDAMYCIN PHOSPHATE</td>
<td>24729-96-2</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: Glycoside (lincosamide) antibiotic.
Chlorinated derivative of lincomycin. It is a mainly bacteriostatic drug used in the treatment of serious anaerobic infections and also used for some Gram-positive infections.

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, 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. Clindamycin phosphate is incompatible with natural rubber closures.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: CLINDAMYCIN PHOSPHATE</th>
<th>CAS #: 24729-96-2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TWA</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</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
SAFETY DATA SHEET

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PHYSICAL STATE</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION</td>
<td>White to off-white, hygroscopic, crystalline powder. Is odorless or practically odorless.</td>
</tr>
<tr>
<td>SOLUBILITY</td>
<td>Freely soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, in benzene, and in ether.</td>
</tr>
<tr>
<td>ODOR</td>
<td>Odorless or practically odorless</td>
</tr>
<tr>
<td>FLAMMABILITY</td>
<td>May be combustible at high temperature</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ODOR THRESHOLD</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>3.5 - 4.5 (1%)</td>
</tr>
<tr>
<td>MELTING POINT</td>
<td>~175 °C, ~347 °F</td>
</tr>
<tr>
<td>BOILING POINT</td>
<td>Not available</td>
</tr>
<tr>
<td>FREEZING POINT</td>
<td>~175 °C, ~347 °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>VAPOR PRESSURE</td>
<td>&lt; 0.0000001 kPa (25°C)</td>
</tr>
<tr>
<td>RELATIVE DENSITY</td>
<td>Not available</td>
</tr>
<tr>
<td>VAPOR DENSITY</td>
<td>Not available</td>
</tr>
<tr>
<td>WATER = 1</td>
<td>log P (OCTANOL-WATER)</td>
</tr>
<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
<td>Not available</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

<table>
<thead>
<tr>
<th>REACTIVITY</th>
<th>Solutions of clindamycin salts have an acid pH and incompatibility may reasonably be expected with alkaline preparations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STABILITY</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>MATERIALS TO AVOID</td>
<td>Aminophylline, ampicillin sodium, barbiturates, calcium gluconate, magnesium sulfate, phenytoin, sodium vitamins of the B group, strong oxidants</td>
</tr>
<tr>
<td>HAZARDOUS DECOMPOSITION PRODUCTS</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other gases may occur</td>
</tr>
<tr>
<td>HAZARDOUS POLYMERIZATION</td>
<td>Will not occur</td>
</tr>
<tr>
<td>POSSIBILITY OF HAZARDOUS REACTION</td>
<td>Not established</td>
</tr>
<tr>
<td>CONDITIONS TO AVOID</td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

SECTION 11: TOXICOLOGICAL INFORMATION
SAFETY DATA SHEET

ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 1832
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

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

SERIOUS EYE DAMAGE/EYE IRRITATION

Causes serious eye irritation (pH 3.5 - 4.5)

REPRODUCTIVE TOXICITY

180 mg/kg/day Reproductivity test
Species: Rat
Result: No adverse fetal effects.
700mg/kg Subcutaneous, 7 - 13 days pregnant
Species: Mouse
Result: Developmental abnormalities musculoskeletal system
2800 mg/kg Intraperitoneal, 7 - 13 days pregnant
Species: Mouse
Result: Fetotoxicity (except death, e.g. stunted fetus)
Although it is unlikely that a breast-fed infant could absorb significant amounts, caution should be exercised when clindamycin is given during breast feeding.

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.
Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity

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

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

Delayed and immediate effects of exposure:
Colitis

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

Medical conditions aggravated by exposure:
Gastrointestinal disease. Impaired kidney function. Impaired liver function

POTENTIAL HEALTH EFFECTS

Inhalation May be harmful if inhaled. May cause respiratory tract irritation. Clindamycin has neuromuscular blocking activity in high doses and may enhance the effect of other drugs with this action, leading to a potential danger of respiratory depression.
Ingestion: Harmful if swallowed. May produce diarrhoea or colitis, nausea, vomiting, abdominal pain or cramps, oesophagitis and an unpleasant or metallic taste.

Skin: May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction like skin rashes and urticaria. Topical application may be associated with local irritation and contact dermatitis; sufficient clindamycin may be absorbed to produce systemic effects.

Eyes: Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable

BIOACCUMULATIVE POTENTIAL
Not available

MOBILITY IN SOIL
Freely soluble in water

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.

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 Appendix A | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65
---|---|---|---|---|---|---|---
CLINDAMYCIN PHOSPHATE 24729-96-2 | N/L | N/L | N/L | N/L | N/L | N/L | N/L

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 PHOSPHATE 24729-96-2</td>
<td>N/L</td>
<td>Listed as Schedule 4*</td>
<td>N/L</td>
</tr>
</tbody>
</table>

*Listed as Clindamycin

**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**

11/2018

**SUPERSEDES**

09/2015

**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.