SAFETY DATA SHEET

1. Identification

Product identifier

Clindamycin Palmitate Hydrochloride

Other means of identification

Catalog number

1137005

Chemical name

L-threo-alpha-D-galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[1-methyl-4-propyl-2-pyrrolidinyl]carbonyl]amino]-1-thio-2-hexadecanoate, monohydrochloride, (2S-trans)-

Recommended use

Specified quality tests and assay use only.

Recommended restrictions

Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

U. S. Pharmacopeia

Address

12601 Twinbrook Parkway

Rockville

MD

20852-1790

United States

Telephone

RS Technical Services

301-816-8129

Website

www.usp.org

E-mail

RSTECH@usp.org

Emergency phone number

CHEMTREC within US & Canada

1-800-424-9300

CHEMTREC outside US & Canada

+1 703-527-3887

2. Hazard(s) identification

Physical hazards

Not classified.

Health hazards

Sensitization, skin

Category 1

Environmental hazards

Not classified.

OSHA defined hazards

Not classified.

Label elements

Signal word

Warning

Hazard statement

May cause an allergic skin reaction.

Precautionary statement

Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.

Response

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 available.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients

Substance

Clindamycin Palmitate Hydrochloride

Chemical name

Common name and synonyms

CAS number

%  

25507-04-4

100
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
May cause an allergic skin reaction.

Provide general supportive measures and treat symptomatically. Treatment of overdose may include the following: Administer activated charcoal as a slurry. Treat moderate to severe pseudomembranous colitis with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against C. difficile colitis. Administration of antiperistaltic antiarrheals is NOT recommended. For pseudomembranous colitis not responding to the above measures, administer oral doses of metronidazole, bacitracin, cholestyramine, or vancomycin. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. [USP DI 7007 and PDR 2007]

5. Fire-fighting measures

Suitable extinguishing media
Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials. Cool containers exposed to flames with water until well after the fire is out.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

| Material name: Clindamycin Palmitate Hydrochloride (CAS 25507-04-4) | TWA | 0.1 mg/m3 |

Material name: Clindamycin Palmitate Hydrochloride

USP SDS US

1137005 Version #: 03 Revision date: 03-07-2017 Issue date: 09-04-2007
Biological exposure limits

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment

**Eye/face protection**

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**

**Hand protection**

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Other**

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory protection**

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

9. Physical and chemical properties

**Appearance**

- **Physical state**: Solid.
- **Form**: Powder.
- **Color**: White. Off-white.

**Odor**

- **Odor threshold**: Not available.

**pH**

- **pH**: 2.3 - 3.8 (1% solution)

**Melting point/freezing point**

- **Melting point/freezing point**: 334.4 - 352.4 °F (168 - 178 °C)

**Initial boiling point and boiling range**

- **Initial boiling point and boiling range**: Not available.

**Flash point**

- **Flash point**: Not available.

**Evaporation rate**

- **Evaporation rate**: Not available.

**Flammability (solid, gas)**

- **Flammability (solid, gas)**: Not available.

**Upper/lower flammability or explosive limits**

- **Flammability limit - lower (%)**: Not available.
- **Flammability limit - upper (%)**: Not available.
- **Explosive limit - lower (%)**: Not available.
- **Explosive limit - upper (%)**: Not available.

**Vapor pressure**

- **Vapor pressure**: < 0.0000001 kPa at 25 °C

**Vapor density**

- **Vapor density**: Not available.

**Relative density**

- **Relative density**: Not available.

**Solubility(ies)**

- **Solubility (water)**: Freely soluble.

**Auto-ignition temperature**

- **Auto-ignition temperature**: Not available.

**Decomposition temperature**

- **Decomposition temperature**: Not available.

**Viscosity**

- **Viscosity**: Not available.
Other information
Chemical family  Glycoside (lincosamide) antibiotic.
Molecular formula  C34H63ClN2O6S . HCl
Molecular weight  699.85

10. Stability and reactivity
Reactivity  The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability  Material is stable under normal conditions.
Possibility of hazardous reactions  No dangerous reaction known under conditions of normal use.
Conditions to avoid  Contact with incompatible materials. None known.
Incompatible materials  Oxidizing agents.
Hazardous decomposition products  NOx. SOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
Inhalation  Knowledge about health hazard is incomplete.
Skin contact  May cause an allergic skin reaction.
Eye contact  Knowledge about health hazard is incomplete.
Ingestion  Based on information from therapeutic use, this material may cause: Pseudomembranous colitis.

Symptoms related to the physical, chemical, and toxicological characteristics

Information on toxicological effects
Acute toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Palmitate Hydrochloride (CAS 25507-04-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 5000 mg/Kg</td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td>Knowledge about health hazard is incomplete.</td>
<td></td>
</tr>
<tr>
<td><strong>Serious eye damage/eye irritation</strong></td>
<td>Knowledge about health hazard is incomplete.</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory or skin sensitization</strong></td>
<td>Knowledge about health hazard is incomplete.</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory sensitization</strong></td>
<td>Knowledge about health hazard is incomplete.</td>
<td></td>
</tr>
<tr>
<td><strong>Skin sensitization</strong></td>
<td>May cause an allergic skin reaction.</td>
<td></td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td>Knowledge about mutagenicity is incomplete.</td>
<td></td>
</tr>
<tr>
<td><strong>Mutagenicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ames test (Salmonella typhimurium)</td>
<td>Result: Negative.</td>
<td></td>
</tr>
<tr>
<td>Micronucleus assay</td>
<td>Result: Negative.</td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutagenicity, AS52/XPRT mutation assay</td>
<td>Result: Negative.</td>
<td></td>
</tr>
<tr>
<td>Mutagenicity, CHO/HPRT mutation assay</td>
<td>Result: Negative.</td>
<td></td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>Knowledge about carcinogenicity is incomplete.</td>
<td></td>
</tr>
</tbody>
</table>

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity  Knowledge about health hazard is incomplete.
Reproductivity
250 mg/kg/day Reproductivity / Developmental, Not teratogenic (administered subcutaneously).
300 mg/kg/day Reproductivity, No effects on fertility or mating ability (administered orally).
Species: Rat
600 mg/kg/day Reproductivity / Developmental, Not teratogenic (administered orally).
Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.
Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information
Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability No data is available on the degradability of this product.
Bioaccumulative potential No data available.
Mobility in soil No data available.
Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations
Disposal instructions Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Local disposal regulations Dispose in accordance with all applicable regulations.
Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT Not regulated as dangerous goods.
IATA Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.
General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information
US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4) Not listed.
SARA 304 Emergency release notification Not regulated.
SARA 302 Extremely hazardous substance
Not listed.
SARA 311/312 Hazardous chemical
Yes
SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.
Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations
US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
Not listed.
US. Massachusetts RTK - Substance List
Not regulated.
US. New Jersey Worker and Community Right-to-Know Act
Not listed.
US. Pennsylvania RTK - Hazardous Substances
Not regulated.
US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.
US. Rhode Island RTK
Not regulated.
US. California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision
Issue date 09-04-2007
Revision date 03-07-2017
Version # 03
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