MATERIAL SAFETY DATA SHEET

Product Name: Clindamycin Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency 224-212-2000

Product Name
Clindamycin Injection, USP

Synonyms
Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-
pyrrolidinecarboxamido)-1-thio-L-threo-α-D-galacto-octopyranoside 2-
(dihydrogen phosphate).

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Clindamycin Phosphate

Chemical Formula
C₁₈H₃₄ClN₂O₈PS

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include disodium edetate and benzyl alcohol; sodium hydroxide and/or hydrochloric acid are added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>15</td>
<td>24729-96-2</td>
<td>GF2625000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Clindamycin Injection, USP is a solution containing clindamycin phosphate, a water soluble ester of the semi-synthetic antibiotic clindamycin. Clinically, it is intended for oral, parenteral, and topical use and indicated for the treatment of serious respiratory tract infections, pelvic inflammatory disease, bacterial vaginosis, hematogenous osteomyelitis and endocarditis. In the workplace, this material should be considered a potential sensitizer and potentially irritating to the skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the gastrointestinal system, blood, liver, kidneys, and skin.

Occupational Exposure Potential
Information on the absorption of this material via inhalation or skin contact is not available. During topical use of formulated gels, clindamycin may be absorbed through skin and mucus membranes.

Signs and Symptoms
None known from workplace exposures. In clinical use, systemic clindamycin has produced...
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diarrhea in up to 20% of patients. Other gastrointestinal effects include nausea, vomiting, abdominal pain or cramps, and esophagitis; an unpleasant or metallic taste has occasionally been reported after high intravenous doses. Pseudomembranous colitis may also occur. Hypersensitivity reactions such as skin rashes and urticaria occur in up to 10% of patients. Other adverse effects include transient leucopenia or occasionally agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, and abnormalities of liver function tests with some cases overt jaundice and hepatic damage that have been reported. Renal dysfunction may occur rarely. Topical use has been associated with local irritation and contact dermatitis; clindamycin may be absorbed through the skin to produce systemic effects.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to clindamycin phosphate or related antibiotics; pre-existing skin, eye, liver, blood, or gastrointestinal ailments.

4. FIRST AID MEASURES

| Eye contact | Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |
| Skin contact | Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |
| Inhalation | Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |
| Ingestion | Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |

5. FIRE FIGHTING MEASURES

| Flammability | None anticipated for this aqueous product. |
| Fire & Explosion Hazard | None anticipated for this aqueous product. |
| Extinguishing media | As with any fire, use extinguishing media appropriate for primary cause of fire. |
| Special Fire Fighting Procedures | No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus. |

6. ACCIDENTAL RELEASE MEASURES

| Spill Cleanup and Disposal | Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations. |

7. HANDLING AND STORAGE

| Handling | No special handling required for hazard control under conditions of normal use. |
| Storage | No special storage is required for hazard control. For product protection, |
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follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions**

No special precautions required for hazard control. Persons with known hypersensitivity to clindamycin phosphate or related antibiotics should consult a health professional prior to handling open containers of this material.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with this material is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended material use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this material.

## 9. PHYSICAL/CHEMICAL PROPERTIES

### Appearance/Physical State

Liquid

### Color

Clear aqueous based solution

### Odor

NA

### Odor Threshold:

NA

### pH:

6.5 (range 5.5 to 7.0)

### Melting point/Freezing point:

NA

### Initial Boiling Point/Boiling Point Range:

NA

### Evaporation Rate:

NA

### Flammability (solid, gas):

NA

### Upper/Lower Flammability or Explosive Limits:

NA

### Vapor Pressure:

NA

### Vapor Density:

NA

### Specific Gravity:

NA

### Solubility:

Clindamycin phosphate is very soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, ether, or benzene.

### Partition coefficient: n-octanol/water:

NA
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Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Not determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), oxides of phosphate and sulfur, and hydrogen chloride.

Hazardous Polymerization
Not anticipated to occur with this material.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1832/2539</td>
<td>mg/kg</td>
<td>Rat/Mouse</td>
</tr>
<tr>
<td>Clindamycin Phosphate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>321/820</td>
<td>mg/kg</td>
<td>Rat/Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation with redness and itching.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation with redness and pain.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions such as skin rashes and urticaria occur in up to 10% of patients.

Reproductive Effects
Fertility studies in rats treated orally with up to 300 mg/kg/day revealed no effects on fertility or mating ability. Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day or subcutaneous doses of clindamycin up to 250 mg/kg/day revealed no evidence of teratogenicity.

Mutagenicity
Clindamycin was negative for genotoxicity in a rat micronucleus test and an Ames Salmonella reversion test.
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Carcinogenicity
Long term studies in animals with clindamycin to evaluate carcinogenic potential have not been conducted.

Target Organ Effects
Based on clinical use, possible target organs include the gastrointestinal system, blood, liver, kidneys, and skin.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product

Persistence/Biodegradability
Not determined for product

Bioaccumulation
Not determined for product

Mobility in Soil
Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

RCRA Status
Not Listed

U.S. OSHA Classification
Possible Sensitizer
Target Organ Toxin
Possible Irritant

GHS Classification
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:
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<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Category</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Signal Word</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Symbol</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Prevention</td>
<td>P260 - Do not breathe dust/fume/gas/mist/vapours/spray.</td>
</tr>
<tr>
<td>Hazard Statement</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Response:</td>
<td>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 attention. Wash hands after handling. Get medical attention if you feel unwell.</td>
</tr>
</tbody>
</table>

**EU Classification***

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Clindamycin Phosphate.

- Classification(s): Not Applicable
- Symbol: Not Applicable
- Indication of Danger: Not Applicable
- Risk Phrases: Not Applicable

**16. OTHER INFORMATION:**

**Notes:**

- ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS: Chemical Abstracts Service Number
- CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT: US Department of Transportation Regulations
- EEL: Employee Exposure Limit
- IATA: International Air Transport Association
- LD50: Dosage producing 50% mortality
- NA: Not applicable/Not available
- NE: Not established
- NIOSH: National Institute for Occupational Safety and Health
- OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
- Prop 65: California Proposition 65
- RCRA: US EPA, Resource Conservation and Recovery Act
- RTECS: Registry of Toxic Effects of Chemical Substances
- SARA: Superfund Amendments and Reauthorization Act
- STEL: 15-minute Short Term Exposure Limit
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TSCA       Toxic Substance Control Act
TWA        8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/09/2011
Obsolete Date: 10/21/2008

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