1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Clindamycin Phosphate Topical Gel

| Trade Name: | Cleocin T |
| Chemical Family: | Mixture |
| Intended Use: | Pharmaceutical product used as antibiotic agent |

2. HAZARDS IDENTIFICATION

Appearance: Colorless gel
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
- **Short Term:** Active ingredient may be harmful if swallowed. May cause eye irritation. May cause mild skin irritation (based on animal data).
- **Known Clinical Effects:** Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused sore throat, fever gastrointestinal disturbances, abnormal liver function tests, kidney dysfunction. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

EU Indication of danger: Irritant

EU Hazard Symbols: Xi

EU Risk Phrases: R43 - May cause sensitization by skin contact.


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Xi;R36-43</td>
<td>1</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbomer</td>
<td>54182-57-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Allantoin</td>
<td>97-59-6</td>
<td>202-592-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol 400</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable
6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Clindamycin Phosphate
- Pfizer OEL TWA-8 Hr: 100µg/m³
- Propylene glycol
  - Australia TWA: 10 mg/m³, 150 ppm, 474 mg/m³
  - Ireland OEL - TWAs: Listed
  - Latvia OEL - TWA: Listed
  - Lithuania OEL - TWA: Listed
- Polyelethylene glycol 400
  - Austria OEL - MAKs: Listed
  - Germany - TRGS 900 - TWAs: 1000 mg/m³
  - Germany (DFG) - MAK: 1000 mg/m³ MAK
  - Slovenia OEL - TWA: Listed

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Color</th>
<th>Molecular Formula</th>
<th>Molecular Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gel</td>
<td>Clear, colorless</td>
<td>Mixture</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable at normal conditions

**Conditions to Avoid:** None known

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>1832 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Para-periosteal</td>
<td>LD 50</td>
<td>321 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD 50</td>
<td>745 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>2359 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD 50</td>
<td>820 mg/kg</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>22,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>20,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LD50</td>
<td>20,800 mg/kg</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 8000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>2280 mg/kg</td>
</tr>
</tbody>
</table>

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Irritation / Sensitization: (Study Type, Species, Severity)**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Study Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
</table>

**Clindamycin Phosphate**
11. TOXICOLOGICAL INFORMATION

Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Polyethylene glycol 400
Eye Irritation  Rabbit  Mild
Skin Irritation  Rabbit  Mild

Propylene glycol
Skin Irritation  Rabbit  Mild
Eye Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Clindamycin Phosphate
6 Month(s)  Rat  Oral  600 mg/kg/day  NOAEL  No effects at maximum dose
6 Month(s)  Dog  Oral  600 mg/kg/day  NOAEL  Gastrointestinal system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Clindamycin Phosphate
Prenatal & Postnatal Development  Rat  Subcutaneous  250 mg/kg  NOAEL  Not teratogenic
Prenatal & Postnatal Development  Rat  Oral  300 mg/kg/day  NOAEL  Not Teratogenic
Prenatal & Postnatal Development  Mouse  Oral  600 mg/kg/day  NOAEL  Not Teratogenic
Prenatal & Postnatal Development  Rabbit  Subcutaneous  5 mg/kg/day  NOAEL  Not Teratogenic, Maternal Toxicity
Reproductive & Fertility  Rat  Oral  300 mg/kg/day  NOAEL  No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Clindamycin Phosphate
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vitro Micronucleus  Rat  Negative

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:  Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
14. TRANSPORT INFORMATION

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant
EU Risk Phrases: R43 - May cause sensitization by skin contact.

EU Safety Phrases: S24 - Avoid contact with skin.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B

Clindamycin Phosphate
EU EINECS/ELINCS List 246-433-0

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 202-785-7

Allantoin
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 202-592-8

Propylene glycol
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 200-338-0

Water, purified
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-791-2</td>
</tr>
</tbody>
</table>

Polyethylene glycol 400

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R43 - May cause sensitization by skin contact.

Data Sources:

Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet