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

Product Identifier

Material Name: Clindamycin Phosphate Topical Solution
Trade Name: CLEOCIN T; DALACIN T; DALACINE T
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
- Serious Eye Damage/Eye Irritation: Category 2A
- Skin Sensitization: Category 1
- Specific target organ systemic toxicity (single exposure): Category 3
- Flammable liquids: Category 3

EU Classification:
- EU Indication of danger: Irritant

EU Risk Phrases:
- R10 - Flammable.
- R36 - Irritating to eyes.
- R43 - May cause sensitization by skin contact.
- R67 - Vapors may cause drowsiness and dizziness.

Label Elements
Signal Word: Warning
Hazard Statements:
- H226 - Flammable liquid and vapor
- H319 - Causes serious eye irritation
- H317 - May cause an allergic skin reaction
- H336 - May cause drowsiness and dizziness
Precautionary Statements:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/Bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P403 + P235 - Store in a well-ventilated place. Keep cool
P501 - Dispose of contents/container in accordance with all local and national regulations
P264 - Wash hands thoroughly after handling
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P363 - Wash contaminated clothing before reuse

Other Hazards

Australian Hazard Classification (NOHSC):

No data available
Hazardous Substance. Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>F; R11</td>
<td>STOT SE 3 (H336)</td>
<td>50</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Xi; R36 R67</td>
<td>Flam. Liq. 2 (H225)</td>
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</tr>
<tr>
<td></td>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Xi; R36-43 Xn; R22</td>
<td>Acute Tox.4 (H302)</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2A (H319)</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit.3 (H316)</td>
<td></td>
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<tr>
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<td></td>
<td></td>
<td>Skin Sens.1 (H317)</td>
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</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

CLINDAMYCIN PHOSPHATE TOPICAL SOLUTION
4. FIRST AID MEASURES

Description of 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 and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

Fire / Explosion Hazards: Flammable liquid. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

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

**Methods and Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity). Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**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

**Precautions for Safe 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.

**Conditions for Safe Storage, Including any Incompatibilities**
- **Storage Conditions:** Store as directed by product packaging.
- **Incompatible Materials:** Oxidising agents, Acids, Bases.

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Isopropyl alcohol**
- **ACGIH Threshold Limit Value (TWA):** 200 ppm
- **ACGIH Threshold Limit Value (STEL):** 400 ppm
- **ACGIH - Biological Exposure Limit:** 40 mg/L
- **Australia STEL:**
  - 500 ppm
  - 1230 mg/m³
- **Australia TWA:**
  - 400 ppm
  - 983 mg/m³
- **Austria OEL - MAKs:**
  - 200 ppm
  - 500 mg/m³
- **Belgium OEL - TWA:**
  - 200 ppm
  - 500 mg/m³
- **Bulgaria OEL - TWA:**
  - 980.0 mg/m³
- **Czech Republic OEL - TWA:**
  - 500 mg/m³
- **Denmark OEL - TWA:**
  - 200 ppm
  - 490 mg/m³
- **Estonia OEL - TWA:**
  - 150 ppm
  - 350 mg/m³
- **Finland OEL - TWA:**
  - 200 ppm
  - 500 mg/m³
- **Germany - TRGS 900 - TWAs:**
  - 200 ppm
  - 500 mg/m³
- **Germany (DFG) - MAK:**
  - 200 ppm
  - 500 mg/m³
- **Germany - Biological Exposure Limit:**
  - 25 mg/L
- **Greece OEL - TWA:**
  - 400 ppm
  - 980 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: Clindamycin Phosphate Topical Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date: 04-Nov-2014</td>
</tr>
<tr>
<td>Version: 3.0</td>
</tr>
</tbody>
</table>

- **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.

- **Personal Protective Equipment:**
  - Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

- **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:**
  - 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>Solution</th>
<th>Color:</th>
<th>Colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Characteristic alcohol odor</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility:   | No data available                             |
| Water Solubility:     | No data available                             |
| pH:                   | No data available                             |
| Melting/Freezing Point (°C): | No data available.                      |
| Boiling Point (°C):   | No data available                             |
| Partition Coefficient: (Method, pH, Endpoint, Value) | No data available.                        |

**Clindamycin Phosphate**

| Decomposition Temperature (°C): | No data available. |
| Evaporation Rate (Gram/s):      | No data available  |
| Vapor Pressure (kPa):           | No data available  |
| Vapor Density (g/ml):           | No data available  |
| Relative Density:               | No data available  |
| Viscosity:                      | No data available  |

**Flammability:**

| Autoignition Temperature (Solid) (°C): | No data available |
| Flammability (Solids):                | No data available |
| Flash Point (Liquid) (°C):            | 24 Closed cup     |
| Upper Explosive Limits (Liquid) (% by Vol.): | 12.7            |
| Lower Explosive Limits (Liquid) (% by Vol.): | 2                |

### 10. STABILITY AND REACTIVITY

| Reactivity: | No data available |
| Chemical Stability: | Stable under normal conditions of use. |

**Possibility of Hazardous Reactions**

- **Oxidizing Properties:** No data available
- **Conditions to Avoid:** Keep away from heat, spark, flames and all other sources of ignition. Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** Oxidising agents, Acids, Bases.

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

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

Short Term: May be harmful if swallowed. May cause skin irritation. Vapors irritating to eyes and respiratory tract. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death.

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.

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

Clindamycin Phosphate
Rat Oral LD50 1832 mg/kg
Rat Para-periosteal LD50 321mg/kg
Rat Intraperitoneal LD50 745mg/kg
Mouse Oral LD50 2359mg/kg
Mouse Intravenous LD50 820mg/kg

Isopropyl alcohol
Rat Oral LD50 > 2000 mg/kg
Mouse Oral LD50 3600 mg/kg
Rat Inhalation LC50-8h 16,000 ppm
Rabbit Dermal LD50 12800 mg/kg
Rat Inhalation LC50 30mg/L

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)

Clindamycin Phosphate
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Isopropyl alcohol
Eye Irritation Rabbit Severe
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

Isopropyl alcohol
20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system
104 Week(s) Rat Inhalation 5000 ppm Kidney
11. TOXICOLOGICAL INFORMATION

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

**Isopropyl alcohol**
- Prenatal & Postnatal Development: Rat, Inhalation, 7,000 ppm, LOAEL, Maternal toxicity, Fetotoxicity, Embryotoxicity
- 2 Generation Reproductive Toxicity: Rat, Oral, 1000 mg/kg/day, LOAEL, Maternal Toxicity, Fetal mortality
- Prenatal & Postnatal Development: Rat, Oral, 1200 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

**Isopropyl alcohol**
- Bacterial Mutagenicity (Ames): Salmonella, Negative
- Mammalian Cell Mutagenicity: HGPRT Chinese Hamster Ovary (CHO) cells, Negative
- In Vitro Sister Chromatid Exchange: Negative

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

**Isopropyl alcohol**
- IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:
- No data available

Persistence and Degradability:
- No data available

Bio-accumulative Potential:
- No data available

Mobility in Soil:
- No data available
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

The following refers to all categories of classifications unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN 1993</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name:</td>
<td>Flammable liquid, n.o.s. (contains isopropanol)</td>
</tr>
<tr>
<td>Transport hazard class(es):</td>
<td>3</td>
</tr>
<tr>
<td>Packing group:</td>
<td>III</td>
</tr>
<tr>
<td>Flash Point (°C):</td>
<td>24</td>
</tr>
</tbody>
</table>

Exceptions: For small quantities packed in combination packaging, exceptions may apply. Please refer to the applicable dangerous goods regulations for additional information.

| Flash Point (°C): | 24 |

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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

Isopropyl alcohol

| CERCLA/SARA 313 Emission reporting | 1.0 % |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 200-661-7 |
15. REGULATORY INFORMATION

Clindamycin Phosphate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: 246-433-0

Propylene glycol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-338-0

Water, purified
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
- Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness
- Flammable liquids-Cat.3; H225 - Highly flammable liquid and vapor
- Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation
- Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xn - Harmful
Xi - Irritant
F - Highly flammable

R11 - Highly flammable.
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R67 - Vapors may cause drowsiness and dizziness.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 14 - Transport Information. Updated Section 10 - Stability and Reactivity. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information.

Revision date: 04-Nov-2014
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet