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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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

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 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

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>Ingredient</th>
<th>CAS Number</th>
<th>EINECS/ELINCS List</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>STOT SE 3 (H336), Flam. Liq. 2 (H225), Eye Irrit. 2A (H319)</td>
</tr>
<tr>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Acute Tox.4 (H302), Eye Irrit.2A (H319), Skin Irrit.3 (H316), Skin Sens.1 (H317)</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</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 firefighting 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. Cleanup 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
- **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>
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<td>Material Name: Clindamycin Phosphate Topical Solution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure Limits</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hungary OEL - TWA</td>
<td>500 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>200 ppm</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>980 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>350 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>350 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>980 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>900 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>81 ppm</td>
</tr>
<tr>
<td></td>
<td>200 mg/m³</td>
</tr>
<tr>
<td>Romania - Biological Exposure Limit:</td>
<td>50 mg/L</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
</tr>
<tr>
<td>Spain - Biological Exposure Limit:</td>
<td>40 mg/L</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>350 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
</tr>
</tbody>
</table>

Clindamycin Phosphate
Pfizer OEL TWA-8 Hr: 100µg/m³

Propylene glycol
Australia TWA 150 ppm
474 mg/m³
10 mg/m³
Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³
Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

Exposure Controls
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). Contact your safety and health professional or safety equipment
supplier for assistance in selecting the correct protective clothing/equipment based on an
assessment of the workplace conditions, other chemicals used or present in the workplace and
specific operational processes.

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is
possible and for bulk processing operations. (Protective gloves must meet the standards in
accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the
standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Odor: Characteristic alcohol odor
Molecular Formula: Mixture
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
No data available
Isopropyl alcohol
No data available
Propylene glycol
No data available
Water, purified
No data available
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.
10. STABILITY AND REACTIVITY

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.

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 LD 50 321mg/kg
- Rat Intraperitoneal LD 50 745mg/kg
- Mouse Oral LD 50 2359mg/kg
- Mouse Intravenous LD 50 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

Propylene glycol
- Rat Oral LD 50 22,000 mg/kg
- Mouse Oral LD 50 24,900mg/kg
- Rabbit Dermal LD 50 20,800mg/kg

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
11. TOXICOLOGICAL INFORMATION

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

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
  \textit{In Vitro} Micronucleus  Rat  Negative

Isopropyl alcohol
- Bacterial Mutagenicity (Ames)  Salmonella  Negative
- Mammalian Cell Mutagenicity  HGPRT Chinese Hamster Ovary (CHO) cells  Negative
  \textit{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.

UN number: UN 1993
UN proper shipping name: Flammable liquid, n.o.s. (contains isopropanol)
Transport hazard class(es): 3
Packing group: III
Flash Point (°C): 24

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

Isopropyl alcohol
### 15. REGULATORY INFORMATION

| 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 |

**Clindamycin Phosphate**

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

**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 |

**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 |

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### 16. OTHER INFORMATION

**Text of CLP/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

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 31-Jul-2018

**Prepared by:** Product Stewardship Hazard Communication

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