



# SAFETY DATA SHEET

Revision date: 25-Jul-2018

Version: 3.1

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

### Product Identifier

**Material Name:** Clindamycin Phosphate Topical Gel

**Trade Name:** CLEOCIN; DALACIN

**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  
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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

Skin Sensitization: Category 1

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H317 - May cause an allergic skin reaction

**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P271 - Use only outdoors or in a well-ventilated area  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
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

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### 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

#### Hazardous

| Ingredient            | CAS Number | EU EINECS/ELINCS List | GHS Classification   | % |
|-----------------------|------------|-----------------------|--|---|
| Clindamycin Phosphate | 24729-96-2 | 246-433-0             | Acute Tox.4 (H302)<br>Eye Irrit.2A (H319)<br>Skin Irrit.3 (H316)<br>Skin Sens.1 (H317) | 1 |
| Propylene glycol      | 57-55-6    | 200-338-0             | Not Listed   | * |

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

#### Additional Information:

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 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. Flush area with large amounts of water. Use soap. Seek medical attention.

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**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 CO<sub>2</sub>, 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:** Not applicable

### 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:** 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.

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Clindamycin Phosphate

Pfizer OEL TWA-8 Hr: 100µg/m<sup>3</sup>

#### Polyethylene glycol 400

Austria OEL - MAKs 1000 mg/m<sup>3</sup>  
Germany - TRGS 900 - TWAs 1000 mg/m<sup>3</sup>  
Germany (DFG) - MAK 1000 mg/m<sup>3</sup> average molecular weight 200-600  
Slovakia OEL - TWA 1000 mg/m<sup>3</sup>  
Slovenia OEL - TWA 1000 mg/m<sup>3</sup>  
Switzerland OEL -TWAs 1000 mg/m<sup>3</sup>

#### Propylene glycol

Australia TWA 150 ppm  
474 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 150 ppm  
470 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
Latvia OEL - TWA 7 mg/m<sup>3</sup>  
Lithuania OEL - TWA 7 mg/m<sup>3</sup>

#### 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.)

##### 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.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

|                           |                    |                          |                    |
|---------------------------|--------------------|--------------------------|--------------------|
| <b>Physical State:</b>    | Gel                | <b>Color:</b>            | Clear, colorless   |
| <b>Odor:</b>              | No data available. | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b> | Mixture            | <b>Molecular Weight:</b> | Mixture            |

|                                     |                    |
|-------------------------------------|--------------------|
| <b>Solvent Solubility:</b>          | No data available  |
| <b>Water Solubility:</b>            | No data available  |
| <b>pH:</b>                          | No data available. |
| <b>Melting/Freezing Point (°C):</b> | No data available  |
| <b>Boiling Point (°C):</b>          | No data available. |

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Clindamycin Phosphate**

No data available

**Polyethylene glycol 400**

No data available

**Propylene glycol**

No data available

**Allantoin**

No data available

**Methylparaben**

No data available

**Carbomer**

No data available

**Water, purified**

No data available

**Decomposition Temperature (°C):** No data available.

|                                   |                   |
|-----------------------------------|-------------------|
| <b>Evaporation Rate (Gram/s):</b> | No data available |
| <b>Vapor Pressure (kPa):</b>      | No data available |
| <b>Vapor Density (g/ml):</b>      | No data available |
| <b>Relative Density:</b>          | No data available |
| <b>Viscosity:</b>                 | No data available |

**Flammability:**

|   |                   |
|---|-------------------|
| <b>Autoignition Temperature (Solid) (°C):</b>       | No data available |
| <b>Flammability (Solids):</b>                       | No data available |
| <b>Flash Point (Liquid) (°C):</b>                   | No data available |
| <b>Upper Explosive Limits (Liquid) (% by Vol.):</b> | No data available |
| <b>Lower Explosive Limits (Liquid) (% by Vol.):</b> | No data available |

### 10. STABILITY AND REACTIVITY

|   |  |
|---|--|
| <b>Reactivity:</b>                        | No data available  |
| <b>Chemical Stability:</b>                | Stable at normal conditions  |
| <b>Possibility of Hazardous Reactions</b> |  |
| <b>Oxidizing Properties:</b>              | No data available  |
| <b>Conditions to Avoid:</b>               | Fine particles (such as dust and mists) may fuel fires/explosions. |
| <b>Incompatible Materials:</b>            | As a precautionary measure, keep away from strong oxidizers        |
| <b>Hazardous Decomposition Products:</b>  | No data available  |

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### 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:

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.

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

##### Clindamycin Phosphate

|       |                 |       |            |
|-------|-----------------|-------|------------|
| Rat   | Oral            | LD 50 | 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   |

##### 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     |

##### 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

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### 11. TOXICOLOGICAL INFORMATION

|                                  |        |                          |       |                                    |
|----------------------------------|--------|--------------------------|-------|------------------------------------|
| 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

|                                       |  |
|---------------------------------------|--|
| <b>Environmental Overview:</b>        | Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. |
| <b>Toxicity:</b>                      | No data available  |
| <b>Persistence and Degradability:</b> | No data available  |
| <b>Bio-accumulative Potential:</b>    | No data available  |
| <b>Mobility in Soil:</b>              | 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 modes of transportation unless specified below.

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

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### 15. REGULATORY INFORMATION

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

##### Allantoin

|   |            |
|---|------------|
| 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                       | 202-592-8  |

##### Carbomer

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

##### Clindamycin Phosphate

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

##### Methylparaben

|   |            |
|---|------------|
| 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                       | 202-785-7  |

##### Polyethylene glycol 400

|   |                          |
|---|--------------------------|
| CERCLA/SARA 313 Emission reporting                            | Not Listed               |
| California Proposition 65                                     | Not Listed               |
| Inventory - United States TSCA - Sect. 8(b)                   | Present                  |
| Australia (AICS):   | Present                  |
| Standard for the Uniform Scheduling<br>for Drugs and Poisons: | Schedule 2<br>Schedule 3 |
| EU EINECS/ELINCS List   | Not Listed               |

##### 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<br>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 |



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### 15. REGULATORY INFORMATION

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

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction  
Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

**Revision date:** 25-Jul-2018  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**