SAFETY DATA SHEET

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

Product Identifier

Material Name: Clindamycin Phosphate Sterile Solution
Trade Name:
DALACIN C; DALACIN; CLEOCIN; DALACINE
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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Skin Corrosion/Irritation: Category 3
Serious Eye Damage/Eye Irritation: Category 2A
Skin Sensitization: Category 1

Label Elements

Signal Word:
Warning

Hazard Statements:
H319 - Causes serious eye irritation
H316 - Causes mild skin irritation
H317 - May cause an allergic skin reaction

Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
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
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental first aid instructions on this label)
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations
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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edetate disodium</td>
<td>139-33-3</td>
<td>205-358-3</td>
<td>Not Listed</td>
<td>&lt;0.1</td>
<td></td>
</tr>
<tr>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Acute Tox.4 (H302)</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2A (H319)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit.3 (H316)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Sens.1 (H317)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4 (H332)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</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.
- 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 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: Formation of toxic gases is possible during heating or fire.
Products:
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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
Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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
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/m³

Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 40 mg/m³
Finland OEL - TWA 10 ppm
        45 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
Poland OEL - TWA 240 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.)

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: No data available.
Molecular Formula: Mixture

Color: Clear, colorless
Odor Threshold: No data available.
Molecular Weight: 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)
Clindamycin Phosphate
No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Water for Injection
No data available

Benzyl Alcohol
No data available

Edetate disodium
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):  No data available
- Upper Explosive Limits (Liquid) (% by Vol.):  No data available
- Lower Explosive Limits (Liquid) (% by Vol.):  No data available

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:  Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials:  As a precautionary measure, keep away from strong oxidizers
- 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:  Active ingredient may be harmful if swallowed. May cause eye irritation; May cause skin irritation. (based on components).

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
11. TOXICOLOGICAL INFORMATION

Benzyl Alcohol
Rat  Oral  LD50  1230 mg/kg
Rat  Para-periosteal  LD50  53mg/kg
Rat  Inhalation  LC50  >4.178mg/L

Edetate disodium
Rat  Oral  LD50  2000-2200 mg/kg

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

Clindamycin Phosphate
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Benzyl Alcohol
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Minimal
Skin Irritation  Guinea Pig  Moderate

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.

Toxicity:

CLINDAMYCIN PHOSPHATE STERILE SOLUTION
**SAFETY DATA SHEET**

**Material Name:** Clindamycin Phosphate Sterile Solution  
**Revision date:** 31-Jul-2018  
**Version:** 2.2

---

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

**Benzyl Alcohol**

*Pimephales promelas* (Fathead Minnow)  
EPA  
LC50  
96 Hours  
460 mg/L

*Daphnia magna* (Water Flea)  
OECD  
EC50  
48 Hours  
230 mg/L

*Pseudokirchneriella subcapitata* (Green Alga)  
OECD  
EC50  
72 Hours  
500 mg/L

**Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

**Benzyl Alcohol**

*Daphnia magna* (Water Flea)  
OECD  
21 Day(s)  
EC50  
66 mg/L  
Reproduction

---

### 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.

---

### 15. REGULATORY INFORMATION

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

*Water for Injection*
SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution

Revision date: 31-Jul-2018

Version: 2.2

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>205-358-3</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
<tr>
<td>Clindamycin Phosphate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>246-433-0</td>
</tr>
<tr>
<td>Clindamycin Phosphate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>246-433-0</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>246-433-0</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
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. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

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

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