



# SAFETY DATA SHEET

Revision date: 13-Jun-2016

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## 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

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## 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

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**Other Hazards Note:**

No data available

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	%
Edetate disodium	139-33-3	205-358-3	Not Listed	<0.1
Clindamycin Phosphate	24729-96-2	246-433-0	Acute Tox.4 (H302) Eye Irrit.2A (H319) Skin Irrit.3 (H316) Skin Sens.1 (H317)	15
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<1.0

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	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 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.

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### 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:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 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:** 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

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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Clindamycin Phosphate

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

#### Benzyl Alcohol

Bulgaria OEL - TWA 5.0 mg/m<sup>3</sup>

Czech Republic OEL - TWA 40 mg/m<sup>3</sup>

Finland OEL - TWA 10 ppm

45 mg/m<sup>3</sup>

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Poland OEL - TWA 240 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).

##### 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

#### Physical State:

Solution

#### Color:

Clear, colorless

#### Odor:

No data available.

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### 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

#### 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

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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

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

#### Clindamycin Phosphate

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### 11. TOXICOLOGICAL INFORMATION

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 NOEL No effects at maximum dose  
6 Month(s) Dog Oral 600 mg/kg/day NOEL Gastrointestinal system

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

##### Clindamycin Phosphate

Prenatal & Postnatal Development Rat Subcutaneous 250 mg/kg NOEL Not teratogenic  
Prenatal & Postnatal Development Rat Oral 300 mg/kg/day NOEL Not Teratogenic  
Prenatal & Postnatal Development Mouse Oral 600 mg/kg/day NOEL Not Teratogenic  
Prenatal & Postnatal Development Rabbit Subcutaneous 5 mg/kg/day NOEL Not Teratogenic, Maternal Toxicity  
Reproductive & Fertility Rat Oral 300 mg/kg/day NOEL 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:

##### 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

#### Persistence and Degradability:

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### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

#### Benzyl Alcohol

OECD Activated sludge Ready 92% After 14 Day(s) Ready

**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 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

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

#### Edetate disodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	205-358-3
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#### Clindamycin Phosphate

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

#### Benzyl Alcohol

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	202-859-9

### 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

<b>Data Sources:</b>	Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.
<b>Reasons for Revision:</b>	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information. Updated Section 8 - Exposure Controls / Personal Protection.
<b>Revision date:</b>	13-Jun-2016
<b>Prepared by:</b>	Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**