



# SAFETY DATA SHEET

Revision date: 12-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 Vaginal Cream

**Trade Name:** CLEOCIN; DALACIN; SOBELIN

**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

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  
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  
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  
P501 - Dispose of contents/container in accordance with all local and national regulations

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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) Eye Irrit.2A (H319) Skin Irrit.3 (H316) Skin Sens.1 (H317)	2
Mineral oil	8012-95-1	232-384-2	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Benzyl Alcohol	100-51-6	202-859-9	Acute Tox.4 (H302) Acute Tox.4 (H332)	<5

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Cetyl Palmitate	540-10-3	208-736-6	Not Listed	*
Cetyl/Stearyl alcohol	67762-27-0	267-008-6	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Polysorbate 60	9005-67-8	Not Listed	Not Listed	*
Sorbitan monostearate	1338-41-6	215-664-9	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. Seek medical attention immediately.

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- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- 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:** 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

Avoid contact with eyes. Avoid prolonged or repeated contact with 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

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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>

#### Mineral oil

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
Belgium OEL - TWA	5 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	5 mg/m <sup>3</sup>
Denmark OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Greece OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	5 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 mg/m <sup>3</sup>
Romania OEL - TWA	5 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm
	1 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Spain OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Vietnam OEL - TWAs	5 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>

#### 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Cream	<b>Color:</b>	White
<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>	3-6		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Clindamycin Phosphate</b>	No data available		
<b>Water, purified</b>	No data available		
<b>Sorbitan monostearate</b>	No data available		
<b>Polysorbate 60</b>	No data available		
<b>Propylene glycol</b>	No data available		
<b>Stearic acid</b>	No data available		
<b>Cetyl/Stearyl alcohol</b>	No data available		
<b>Mineral oil</b>	No data available		
<b>Cetyl Palmitate</b>	No data available		
<b>Benzyl Alcohol</b>	No data available		
<b>Decomposition Temperature (°C):</b>	No data available.		

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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 at normal conditions  
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:** May be harmful if swallowed. May cause eye 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

#### Polysorbate 60

Rat Oral LD50 64,000 mg/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

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### 11. TOXICOLOGICAL INFORMATION

#### Stearic acid

Rat Oral LD50 > 4640 mg/kg  
Rabbit Dermal LD50 > 5000mg/kg

#### Benzyl Alcohol

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

##### Propylene glycol

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

##### Stearic acid

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Mild

##### Mineral oil

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

##### Cetyl Palmitate

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

##### Stearic acid

30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue

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### 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

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Clindamycin Phosphate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Micronucleus	Rat	Negative

##### Stearic acid

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Unscheduled DNA Synthesis	<i>E. coli</i>	Negative

##### Stearic acid

26 Week(s)	Rat	Subcutaneous	0.5 mg/kg/week	NOAEL	Not carcinogenic
52 Week(s)	Mouse	Subcutaneous	0.05 mg/kg/week	LOAEL	Tumors

**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

<i>Pimephales promelas</i> (Fathead Minnow)	EPA	LC50	96 Hours	460 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	EC50	48 Hours	230 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EC50	72 Hours	500 mg/L

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

##### Benzyl Alcohol

<i>Daphnia magna</i> (Water Flea)	OECD	21 Day(s)	EC50	66 mg/L	Reproduction
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**Persistence and Degradability:** No data available

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

##### Benzyl Alcohol

OECD	Activated sludge	Ready	92% After	14 Day(s)	Ready
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**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available



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### 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

#### Cetyl Palmitate

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	208-736-6

#### Clindamycin Phosphate

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

#### Cetyl/Stearyl 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	267-008-6

#### Mineral oil

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	232-384-2
<b>Water, purified</b>	
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
<b>Stearic acid</b>	
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	200-313-4
<b>Polysorbate 60</b>	
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	Not Listed
<b>Sorbitan monostearate</b>	
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	215-664-9
<b>Propylene glycol</b>	
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
<b>Benzyl Alcohol</b>	
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

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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:** 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. Updated Section 12 - Ecological Information.

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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**