



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Clindamycin Phosphate Vaginal Cream**

**Trade Name:** CLEOCIN; DALACIN  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Clindamycin Phosphate	24729-96-2	246-433-0	2
Stearic acid	57-11-4	200-313-4	*
Mineral oil	8012-95-1	232-384-2	*
Propylene glycol	57-55-6	200-338-0	*

Ingredient	CAS Number	EU EINECS List	%
Mixed Fatty Acid Esters	Not Assigned	Not listed	*
Polysorbate 60	9005-67-8	Not listed	*
Sorbitan monostearate	1338-41-6	215-664-9	*
Cetyl/Stearyl alcohol	67762-27-0	267-008-6	*
Water, purified	7732-18-5	231-791-2	*
Benzyl Alcohol	100-51-6	202-859-9	*

**Additional Information:** \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** White to off-white cream  
**Signal Word:** WARNING

**Statement of Hazard:** May be harmful if swallowed.  
May cause allergic reaction.

### Additional Hazard Information:

**Short Term:** May cause eye irritation (based on components) May cause mild skin irritation (based on animal data).

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**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.

**EU Indication of danger:** Irritant

**EU Hazard Symbols:**



**EU Risk Phrases:**

R43 - May cause sensitization by skin contact.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. 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:** Due to the nature of this material first aid is not normally required. If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

**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.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

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**Measures for Environmental Protections:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**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

**General Handling:**

Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. Wash thoroughly after handling.

**Storage Conditions:**

Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Clindamycin Phosphate**

Pfizer OEL TWA-8 Hr:

0.1mg/m<sup>3</sup>

**Sorbitan monostearate**

ACGIH Threshold Limit Value (TWA)

= 10 mg/m<sup>3</sup> TWA except stearates of toxic metals

Australia TWA

= 10 mg/m<sup>3</sup> TWA

**Mineral oil**

OSHA - Final PELs - TWAs:

= 5 mg/m<sup>3</sup> TWA

ACGIH Threshold Limit Value (TWA)

= 5 mg/m<sup>3</sup> TWA sampled by method that does not collect vapor

ACGIH Threshold Limit Value (STEL)

= 10 mg/m<sup>3</sup> STEL

ACGIH OELs - Notice of Intended Changes

Listed

Australia TWA

= 5 mg/m<sup>3</sup> TWA

**Propylene glycol**

Australia TWA

= 10 mg/m<sup>3</sup> TWA

= 150 ppm TWA

= 474 mg/m<sup>3</sup> TWA

**Analytical Method:**

Analytical method available for clindamycin. Contact Pfizer Inc for further information.

**Engineering Controls:**

Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:**

Not required for the normal use of this product. Individuals with known sensitivity should wear protective gloves to avoid skin contact.

**Eyes:**

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:**

Not required for the normal use of this product. Wear protective clothing when working with large quantities. Individuals with known sensitivity should wear long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this material.

**Respiratory protection:**

Not required for the normal use of this product. 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:

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<b>Physical State:</b>	Cream	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>pH:</b>	3-6		

## 10. STABILITY AND REACTIVITY

**Stability:** Stable at normal conditions  
**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.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

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

#### **Clindamycin Phosphate**

Rat Oral LD 50 1832 mg/kg  
Rat Intravenous LD 50 321 mg/kg  
Rat Intraperitoneal LD 50 745 mg/kg  
Mouse Oral LD 50 2359 mg/kg  
Mouse Intravenous LD 50 820 mg/kg

#### **Benzyl Alcohol**

Rat Oral LD50 1.23 g/kg  
Rat Intravenous LD50 53 mg/kg

#### **Polysorbate 60**

Rat Oral LD50 64,000 mg/kg

#### **Propylene glycol**

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 mg/kg

#### **Stearic acid**

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

#### **Benzyl Alcohol**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Moderate  
Skin Irritation Guinea Pig Moderate

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### Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

### Stearic acid

Skin Irritation Rabbit Mild

### Mineral oil

Eye Irritation Rabbit Moderate

Skin 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

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.

#### Mineral oil

**IARC:** Group 3

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

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

## 15. REGULATORY INFORMATION

EU Symbol: Xi  
EU Indication of danger: Irritant

EU Risk Phrases:  
R43 - May cause sensitization by skin contact.

EU Safety Phrases:  
S24 - Avoid contact with skin.  
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:  
WARNING  
May be harmful if swallowed.  
May cause allergic reaction.

### Canada - WHMIS: Classifications

WHMIS hazard class:  
Class D, Division 2, Subdivision B



Clindamycin Phosphate  
EU EINECS List 246-433-0

Polysorbate 60  
Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present

Sorbitan monostearate  
Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 215-664-9

Cetyl/Stearyl alcohol  
Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 267-008-6

Stearic acid  
Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 200-313-4

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### Mineral oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-384-2

### Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

### Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-859-9

### Propylene glycol

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

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

**Prepared by:** Corporate Occupational Toxicology & Hazard Assessment

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.

**End of Safety Data Sheet**