



# MATERIAL SAFETY DATA SHEET

Revision date: 27-Jul-2010

Version: 2.0

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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  
Contact E-Mail: pfizer-MSDS@pfizer.com

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

### Material Name: Clindamycin Palmitate Hydrochloride for Oral Solution

Trade Name:	Cleocin Pediatric Flavored Granules; Dalacin C Flavored Granules
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

Appearance: Granules  
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:  
Known Clinical Effects:

Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Harmful

EU Hazard Symbols:

Xi



Australian Hazard Classification (NOHSC):

R43 - May cause sensitization by skin contact.  
Hazardous Substance. Non-Dangerous Goods.

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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Clindamycin Hydrochloride Palmitate	25507-04-4	Not Listed	Xi;R43	3.8
Sucrose	57-50-1	200-334-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ethylparaben	120-47-8	204-399-4	Not Listed	*
Simethicone	8050-81-5	Not Listed	Not Listed	*
Poloxalene	9003-11-6	Not Listed	Not Listed	*
Cherry flavor, artificial	NOT ASSIGNED	Not Listed	Not Listed	*
Dextrin	9004-53-9	232-675-4	Not Listed	*

#### Additional Information:

\* Proprietary

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

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**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:** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Clindamycin Hydrochloride Palmitate

Pfizer OEL TWA-8 Hr: 100µg/m<sup>3</sup>, (as free base)

#### Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

**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. 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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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:** Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Granules  
**Color:** No data available.  
**Molecular Formula:** Mixture  
**Molecular Weight:** Mixture  
**Solubility:** Soluble: Water

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**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 Hydrochloride Palmitate

Rat Oral LD 50 > 5000 mg/kg  
Rat Para-periosteal LD 50 > 5000 mg/kg  
Rat Intraperitoneal LD 50 > 2500 mg/kg  
Mouse Oral LD 50 > 5000 mg/kg  
Mouse Intravenous LD 50 > 5000 mg/kg

#### Sucrose

Rat Oral LD50 29.7 g/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.

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Clindamycin Hydrochloride Palmitate

6 Month(s) Rat Oral 600 mg/kg/day NOAEL No effects at maximum dose  
6 Month(s) Dog Oral 300 mg/kg/day NOAEL No effects at maximum dose

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

#### Clindamycin Hydrochloride Palmitate

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### 11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility	Rat	Oral	300 mg/kg/day	NOAEL	Negative, No effects at maximum dose
Embryo / Fetal Development	Mouse	Oral	600 mg/kg/day	NOAEL	Not Teratogenic, No effects at maximum dose

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

##### Clindamycin Hydrochloride Palmitate

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

##### Sucrose

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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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.

### 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

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

### 15. REGULATORY INFORMATION

EU Symbol:	Xn
EU Indication of danger:	Harmful

R43 - May cause sensitization by skin contact.

#### EU Safety Phrases:

S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.

#### OSHA Label:

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### 15. REGULATORY INFORMATION

#### WARNING

May cause allergic skin reaction.

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision A



#### Sucrose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

#### Ethylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	204-399-4

#### Simethicone

Australia (AICS):	Listed
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#### Poloxalene

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

#### Dextrin

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-675-4

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

**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 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

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**Prepared by:**

Product Stewardship Hazard Communications  
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**