



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

Page 1 of 5

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 Palmitate Hydrochloride for Oral Solution

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Sucrose	57-50-1	200-334-9	*
Clindamycin Hydrochloride Palmitate	25507-04-4	Not listed	3.8

Ingredient	CAS Number	EU EINECS List	%
Non-hazardous ingredients	NOT APPLICABLE	Not listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Granules
Signal Word: WARNING

Statement of Hazard: May cause allergic reaction.

Additional Hazard Information:

Short Term: Not acutely toxic (based on components)
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:



MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Palmitate Hydrochloride for Oral Solution

Page 2 of 5

Revision date: 02-Jan-2007

Version: 1.1

R42/43 - May cause sensitization by inhalation and 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 eye(s) immediately with plenty of water. 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May burn emitting oxides of: carbon nitrogen sulfur chlorine

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 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: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store in a cool, dry place away from light. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Palmitate Hydrochloride for Oral Solution

Page 3 of 5

Revision date: 02-Jan-2007

Version: 1.1

Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Clindamycin Hydrochloride Palmitate

Pfizer OEL TWA-8 Hr: 0.1 mg/m³, (as free base)

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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: Wear protective gloves when working with large quantities.
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.
Respiratory protection: None required under normal conditions of use. 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

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 Intravenous 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

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Palmitate Hydrochloride for Oral Solution

Page 4 of 5

Revision date: 02-Jan-2007

Version: 1.1

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.

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

Clindamycin Hydrochloride Palmitate

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

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

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

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

R42/43 - May cause sensitization by inhalation and skin contact.

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

OSHA Label:
WARNING
May cause allergic reaction.

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Palmitate Hydrochloride for Oral Solution

Page 5 of 5

Revision date: 02-Jan-2007

Version: 1.1

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet