



MATERIAL SAFETY DATA SHEET

Revision date: 24-Aug-2010

Version: 2.1

Page 1 of 8

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

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Material Name: Clindamycin Phosphate Topical Lotion

Trade Name:	Cleocin T
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Colorless lotion
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
Short Term:

May cause mild skin irritation (based on animal data). An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

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 burning sensation of the skin, itching, abnormal redness of skin (erythema). Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 2 of 8
Version: 2.1

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Clindamycin Phosphate	24729-96-2	246-433-0	Xi;R36-43 Xn;R22	1
Glyceryl stearate	123-94-4	204-664-4	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Isostearyl Alcohol	27458-93-1	248-470-8	Not Listed	2.5
Sodium Lauroylsarcosinate	137-16-6	205-281-5	Not Listed	*
Cetyl/Stearyl alcohol	67762-27-0	267-008-6	Not Listed	2.5
Methylparaben	99-76-3	202-785-7	Not Listed	*
Potassium stearate	593-29-3	209-786-1	Not Listed	*
Water, purified	7732-18-5	231-791-2	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

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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.
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.

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:	Not applicable

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 3 of 8
Version: 2.1

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.
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 breathing vapor or mist. 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.

Glycerin, USP

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	50 mg/m ³ MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Clindamycin Phosphate

Pfizer OEL TWA-8 Hr:	100µg/m ³
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Potassium stearate

Lithuania OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Glyceryl stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
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MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 4 of 8
Version: 2.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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).

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. Individuals with known sensitivity should wear long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this material.

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:	Lotion	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable at normal conditions

Conditions to Avoid: None known

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	Para-periosteal	LD 50	321 mg/kg
Rat	Intraperitoneal	LD 50	745 mg/kg
Mouse	Oral	LD 50	2359 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 5 of 8
Version: 2.1

11. TOXICOLOGICAL INFORMATION

Mouse Intravenous LD 50 820 mg/kg

Methylparaben

Mouse Oral LD50 > 8000 mg/kg

Rat Oral LD50 2280 mg/kg

Glycerin, USP

Mouse Oral LD50 4090 mg/kg

Rat Oral LD50 12.6 g/kg

Rabbit Dermal LD50 > 10 g/kg

Rat Inhalation LC50 1hr > 570 mg/m³

Rat Dermal LD 50 >21.9 g/kg

Glyceryl stearate

Rat IP LD50 200 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

Glycerin, USP

Eye Irritation Rabbit Mild

Stearic acid

Skin Irritation Rabbit Moderate

Eye 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 NOEL No effects at maximum dose

6 Month(s) Dog Oral 600 mg/kg/day NOEL Gastrointestinal system

Stearic acid

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

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

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 6 of 8
Version: 2.1

11. TOXICOLOGICAL INFORMATION

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

Clindamycin Phosphate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Micronucleus Rat Negative

Stearic acid

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

Unscheduled DNA Synthesis *E. coli* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

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.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L

Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

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: Xi
EU Indication of danger: Irritant

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 7 of 8
Version: 2.1

15. REGULATORY INFORMATION

EU Safety Phrases:

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

OSHA Label:

WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Isostearyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	248-470-8

Sodium Lauroylsarcosinate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	205-281-5

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-289-5

Clindamycin Phosphate

EU EINECS/ELINCS List	246-433-0
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Cetyl/Stearyl alcohol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	267-008-6

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-785-7

Potassium stearate

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

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Topical Lotion
Revision date: 24-Aug-2010

Page 8 of 8
Version: 2.1

15. REGULATORY INFORMATION

EU EINECS/ELINCS List	209-786-1
Glyceryl stearate	
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	204-664-4
Stearic acid	
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	200-313-4
Water, purified	
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	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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