



MATERIAL SAFETY DATA SHEET

Revision date: 25-Mar-2013

Version: 2.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Clindamycin Phosphate Topical Solution

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

2. HAZARDS IDENTIFICATION

Appearance:	Colorless solution
Signal Word:	WARNING

Statement of Hazard:	Flammable liquid and vapor. Causes eye irritation. Vapors may cause drowsiness and irritation of the eyes or respiratory tract May cause allergic reaction.
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Additional Hazard Information:	
Short Term:	May be harmful if swallowed. May cause skin irritation. Vapors irritating to eyes and respiratory tract. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination. Continued inhalation may result in unconsciousness and death.

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.
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EU Indication of danger:	Irritant
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EU Hazard Symbols:

Xi



EU Risk Phrases:

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2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC):

R10 - Flammable.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R67 - Vapors may cause drowsiness and dizziness.
Hazardous Substance. 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Clindamycin Phosphate	24729-96-2	246-433-0	Xi;R36-43 Xn;R22	1
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Isopropyl alcohol	67-63-0	200-661-7	F;R11 R67 Xi;R36	50

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
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. 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.

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.

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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:	Flammable liquid. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

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:	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity). 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.

Clindamycin Phosphate	
Pfizer OEL TWA-8 Hr:	100µg/m ³
Propylene glycol	
Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Isopropyl alcohol

ACGIH Threshold Limit Value (TWA)	200 ppm
ACGIH Threshold Limit Value (STEL)	400 ppm
ACGIH - Biological Exposure Limit:	40 mg/L
Australia STEL	500 ppm
	1230 mg/m ³
Australia TWA	400 ppm
	983 mg/m ³
Austria OEL - MAKs	200 ppm
	500 mg/m ³
Belgium OEL - TWA	200 ppm
	500 mg/m ³
Bulgaria OEL - TWA	980.0 mg/m ³
Czech Republic OEL - TWA	500 mg/m ³
Denmark OEL - TWA	200 ppm
	490 mg/m ³
Estonia OEL - TWA	150 ppm
	350 mg/m ³
Finland OEL - TWA	200 ppm
	500 mg/m ³
Germany - TRGS 900 - TWAs	200 ppm
	500 mg/m ³
Germany (DFG) - MAK	200 ppm
	500 mg/m ³
Germany - Biological Exposure Limit:	50 mg/L
Greece OEL - TWA	400 ppm
	980 mg/m ³
Hungary OEL - TWA	500 mg/m ³
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm
	980 mg/m ³
Latvia OEL - TWA	350 mg/m ³
Lithuania OEL - TWA	150 ppm
	350 mg/m ³
OSHA - Final PELs - TWAs:	400 ppm
	980 mg/m ³
Poland OEL - TWA	900 mg/m ³
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm
	200 mg/m ³
Romania - Biological Exposure Limit:	50 mg/L
Slovakia OEL - TWA	200 ppm
	500 mg/m ³
Slovenia OEL - TWA	200 ppm
	500 mg/m ³
Spain OEL - TWA	200 ppm
	500 mg/m ³
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm
	350 mg/m ³

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.
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:	Solution	Color:	Colorless
Odor:	Characteristic alcohol odor	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Flash Point (Liquid) (°C):	24 Closed cup
Upper Explosive Limits (Liquid) (% by Vol.):	12.7
Lower Explosive Limits (Liquid) (% by Vol.):	2

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Keep away from heat, spark, flames and all other sources of ignition. Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	Oxidising agents, Acids, Bases.

11. TOXICOLOGICAL INFORMATION

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
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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
Mouse	Intravenous	LD 50	820 mg/kg

Isopropyl alcohol

Rat	Oral	LD50	> 2000 mg/kg
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11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 3600 mg/kg
Rat Inhalation LC50-8h 16,000 ppm
Rabbit Dermal LD50 12800 mg/kg
Rat Inhalation LC50 30 mg/L

Propylene glycol

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

Isopropyl alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
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 NOAEL No effects at maximum dose
6 Month(s) Dog Oral 600 mg/kg/day NOAEL Gastrointestinal system

Isopropyl alcohol

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system
104 Week(s) Rat Inhalation 5000 ppm Kidney

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

Isopropyl alcohol

Prenatal & Postnatal Development Rat Inhalation 7,000 ppm LOAEL Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity Rat Oral 1000 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development Rat Oral 1200 mg/kg/day NOAEL No effects at maximum dose

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

Clindamycin Phosphate

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11. TOXICOLOGICAL INFORMATION

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Micronucleus Rat Negative

Isopropyl alcohol

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity HGPRT Chinese Hamster Ovary (CHO) cells Negative
In Vitro Sister Chromatid Exchange Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Isopropyl alcohol

IARC: Group 3 (Not Classifiable)

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

The following refers to all categories of classifications unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 1993
UN proper shipping name: Flammable liquid, n.o.s. (contains isopropanol)
Transport hazard class(es): 3
Packing group: III
Flash Point (°C): 24

Exceptions: For small quantities packed in combination packaging, exceptions may apply. Please refer to the applicable dangerous goods regulations for additional information.

Flash Point (°C): 24

15. REGULATORY INFORMATION

EU Symbol: Xi

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15. REGULATORY INFORMATION

EU Indication of danger: Irritant

EU Risk Phrases:

R10 - Flammable.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R67 - Vapors may cause drowsiness and dizziness.

EU Safety Phrases:

S16 - Keep away from sources of ignition - No smoking.
S24/25 - Avoid contact with eyes and skin.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

WARNING

Flammable liquid and vapor.

Causes eye irritation.

Vapors may cause drowsiness and irritation of the eyes or respiratory tract

May cause allergic reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision B



Clindamycin Phosphate

EU EINECS/ELINCS List	246-433-0
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Propylene glycol

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

Water, purified

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

Isopropyl alcohol

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	1.0 %
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R67 - Vapors may cause drowsiness and dizziness.

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

Reasons for Revision: Updated Section 14 - Transport Information. Updated Section 10 - Stability and Reactivity.

Prepared by: Product Stewardship Hazard Communication
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