



MATERIAL SAFETY DATA SHEET

Revision date: 19-Aug-2008

Version: 1.7

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

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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.

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.

EU Indication of danger: Irritant

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

Ingredient	CAS Number	EU EINECS/ELINCS List	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.

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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/m³

Isopropyl alcohol

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

Propylene glycol

Australia TWA	= 10 mg/m ³ TWA
	= 150 ppm TWA
	= 474 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 150 ppm TWA
	= 470 mg/m ³ TWA
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

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

Stability: Stable at normal conditions

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition.

Incompatible Materials: Oxidising agents, Acids, Bases.

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

Isopropyl alcohol

Rat Oral LD50 > 2000 mg/kg
Mouse Oral LD50 3600mg/kg
Rat Inhalation LC50-8h 16,000ppm
Rabbit Dermal LD50 12800mg/kg
Rat Inhalation LC50 30mg/L

Propylene glycol

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

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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

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

Isopropyl alcohol

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> 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
OSHA:	Present

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

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13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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.

Proper shipping name: Flammable liquid, n.o.s. (contains isopropanol)
UN / ID No: UN1993
Hazard class: 3
Packing group: III

For small quantities, limited to inner packaging less than or equal to 5.0L (1.3 gal) and outer packaging less than or equal to 30 kg (66 lb.) gross weight, the following may be used:

IATA / ICAO

IATA Proper shipping name: Consumer Commodity
IATA UN / ID No: ID 8000
IATA Hazard Class: 9
IATA Packing Group: Not applicable

IMDG

IMDG Proper shipping name: Flammable Liquid, n.o.s. (contains isopropanol), Ltd Qty
IMDG UN / ID No: UN 1993
IMDG Hazard Class: 3
IMDG Packing Group: III
IMDG additional info: Flashpoint: 24C (75.2F)

DOT

DOT Proper shipping name: Consumer Commodity
DOT Hazard Class: ORM-D

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15. REGULATORY INFORMATION

EU Symbol: Xi
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

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
CERCLA/SARA 313 Emission reporting = 1.0 % de minimis concentration only if manufactured by the strong acid process, no supplier notification
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-661-7

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Propylene glycol

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

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 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport 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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet