

Revision date: 04-Nov-2014

Version: 3.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING Product Identifier

Material Name: Clindamycin Phosphate Topical Solution

Trade Name:CLEOCIN T; DALACIN T; DALACINE TChemical Family:Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet Pfizer Inc Pfizer Pharmaceuticals Group 235 East 42nd Street New York, New York 10017 1-800-879-3477

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A Skin Sensitization: Category 1 Specific target organ systemic toxicity (single exposure): Category 3 Flammable liquids- Category 3

EU Classification:

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.

Label Elements

Signal	Word:	
Hazard	Statements:	

- Warning H226 - Flammable liquid and vapor H319 - Causes serious eye irritation H317 - May cause an allergic skin reaction
- H336 May cause drowsiness and dizziness

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Precautionary Statements:	P210 - Keep away from heat/sparks/open flames/hot surfaces No smoking
	P233 - Keep container tightly closed
	P240 - Ground/Bond container and receiving equipment
	P241 - Use explosion-proof electrical/ventilating/lighting/equipment
	P242 - Use only non-sparking tools
	P243 - Take precautionary measures against static discharge
	P280 - Wear protective gloves/protective clothing/eye protection/face protection
	P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing.
	Rinse skin with water/shower
	P403 + P235 - Store in a well-ventilated place. Keep cool
	P501 - Dispose of contents/container in accordance with all local and national regulations
	P264 - Wash hands thoroughly after handling
	P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove
	contact lenses, if present and easy to do. Continue rinsing
	P337 + P313 - If eye irritation persists: Get medical advice/attention
	P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
	P272 - Contaminated work clothing should not be allowed out of the workplace
	P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
	P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
	P321 - Specific treatment (see supplemental instructions on the administration of antidotes on
	this label)
	P363 - Wash contaminated clothing before reuse



Other Hazards Australian Hazard Classification (NOHSC):

Note:

No data available Hazardous Substance. Dangerous Goods.

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Isopropyl alcohol	67-63-0	200-661-7	F; R11 Xi; R36 R67	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	50
Clindamycin Phosphate	24729-96-2	246-433-0	Xi;R36-43 Xn;R22	Acute Tox.4 (H302) Eye Irrit.2A (H319) Skin Irrit.3 (H316) Skin Sens.1 (H317)	1
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*
Additional Information: For the full text of the R phrases an	safety. In accordance with 2 been withheld as a t	29 CFR 1910.1200, t rade secret.	re been assessed un he exact percentage this Section, see Se	composition of this n	·
4. FIRST AID MEASURES					
Description of First Aid Measures Eye Contact:	Flush with water wh persists, get medica		en for at least 15 mir	nutes. If irritation occu	irs or
Skin Contact:	Remove contaminat assistance if irritatio		n exposed area with s	soap and water. Obta	in medical
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.				
Most Important Symptoms and Effe Symptoms and Effects of Exposure: Medical Conditions Aggravated by Exposure:	For information on p		mptoms of exposure ogical Information.	, See Section 2 - Haz	ards
Indication of the Immediate Medical Notes to Physician:	Attention and Specia None	al Treatment Neede	d		
5. FIRE FIGHTING MEASURE	S				
Extinguishing Media:	Extinguish fires with	CO2, extinguishing	powder, foam, or wat	er.	
Special Hazards Arising from the Su Hazardous Combustion Products:			arbon dioxide, nitrog	en oxides, sulfur oxid	es and othe
Fire / Explosion Hazards:		s are heavier than air	nable or explosive mi and may travel alon		
Advice for Fire-Fighters During all fire fighting activities,	wear appropriate prote	ective equipment, inc	luding self-contained	breathing apparatus	

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.
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

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store as directed by product packaging.
Incompatible Materials:	Oxidising agents, Acids, Bases.
Specific end use(s):	Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

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/m³
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:	25 mg/L
Greece OEL - TWA	400 ppm
	980 mg/m³

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8 EYDOSU		ERSONAL PROTECTION
	ry OEL - TWA	500 mg/m ³
-	OEL - TWAS	200 ppm
	· OELs - Ceilings	400 ppm
Japan	OLL3 - Cennigs	980 mg/m ³
Latvia (OEL - TWA	350 mg/m ³
	nia OEL - TWA	150 ppm
Ennual		350 mg/m ³
OSHA -	Final PELS - TWAs:	400 ppm
		980 mg/m ³
Poland	OEL - TWA	900 mg/m ³
Portuga	al OEL - TWA	200 ppm
-	ia OEL - TWA	81 ppm
		200 mg/m ³
Roman	ia - Biological Exposur	e Limit: 50 mg/L
Russia	OEL - TWA	10 mg/m ³
Slovaki	ia OEL - TWA	200 ppm
		500 mg/m ³
Sloven	ia OEL - TWA	200 ppm
		500 mg/m ³
Spain C	DEL - TWA	200 ppm
		500 mg/m ³
•	Biological Exposure L	-
Swede	n OEL - TWAs	150 ppm
		350 mg/m ³
Switzer	rland OEL -TWAs	200 ppm
		500 mg/m ³
Clindamycin	Phosphate	
-	DEL TWA-8 Hr:	100µg/m³
		100 µ g/
Propylene gly	/col	
	ia TWA	150 ppm
		474 mg/m ³
		10 mg/m ³
Ireland	OEL - TWAs	150 ppm
		470 mg/m ³
		10 mg/m ³
	OEL - TWA	7 mg/m ³
Lithuar	nia OEL - TWA	7 mg/m ³
Analytical Me		Analytical method available for clindamycin. Contact Pfizer Inc for further information.
Exposure Co		
Engine	ering 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.
Person	al Protective	Refer to applicable national standards and regulations in the selection and use of personal
Equipn		protective equipment (PPE).
Equipi		
Hands:		Impervious gloves are recommended if skin contact with drug product is possible and for bulk
Tanus.		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.
Respira	atory 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Odor: Molecular Formula:	Solution Characteristic alcohol odo Mixture	or (Color: Odor Threshold: Molecular Weight:	Colorless No data available. Mixture
Solvent Solubility: Water Solubility: pH: Melting/Freezing Point (°C): Boiling Point (°C): Partition Coefficient: (Method, pH, E Clindamycin Phosphate No data available Isopropyl alcohol No data available Propylene glycol No data available Water, purified No data available Decomposition Temperature (°C):	No data available No data available No data available No data available No data available. Indpoint, Value)			
Evaporation Rate (Gram/s): Vapor Pressure (kPa): Vapor Density (g/ml): Relative Density: Viscosity: Flammablity: Autoignition Temperature (So Flammability (Solids): Flash Point (Liquid) (°C): Upper Explosive Limits (Liquid) Lower Explosive Limits (Liquid)	d) (% by Vol.):	No data availa No data availa 24 Closed cu 12.7 2	able	

10. STABILITY AND REACTIVITY

Reactivity: Chemical Stability: Possibility of Hazardous Reactions	No data available Stable under normal conditions of use.
Oxidizing Properties:	No data available
Conditions to Avoid:	Keep away from heat, spark, flames and all other sources of ignition. Fine particles (such as
Incompatible Materials:	dust and mists) may fuel fires/explosions.
Hazardous Decomposition	Oxidising agents, Acids, Bases.
Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information:

The information included in this section describes the potential hazards of the individual ingredients.

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11. TOXICOLOGICAL 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.			

Acute Toxicity: (Species, Route, End Point, Dose)

Clindamycin Phosphate

RatOralLD 501832 mg/kgRatPara-periostealLD 50321mg/kgRatIntraperitonealLD 50745mg/kgMouseOralLD 502359mg/kgMouseIntravenousLD 50820mg/kg

Isopropyl alcohol

RatOralLD50> 2000 mg/kgMouseOralLD503600 mg/kgRatInhalationLC50-8h16,000 ppmRabbitDermalLD5012800 mg/kgRatInhalationLC5030mg/L

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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11. TOXICOLOGICAL INFORMATION

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 Rabbit Subcutaneous 5 mg/kg/day NOAEL Prenatal & Postnatal Development 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/c	lay LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral 1200 mg/kg/da	ay NOAEL	No effects at maximum dose

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

Clindamycin Phosphate

Carainagan Statua	Nono	of the components of this formulat	ion are listed a
In Vitro Sister Chromatid Excha	nge Negative	9	
Mammalian Cell Mutagenicity	HGPRT Chine	ese Hamster Ovary (CHO) cells	Negative
Bacterial Mutagenicity (Ames)	Salmonella	Negative	
Isopropyl alcohol			
In Vitro Micronucleus Rat	Negative		
Bacterial Mutagenicity (Ames)	Salmonella	Negative	

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

 Isopropyl alcohol
 See below

IARC:	Group 3 (Not Classifiable)
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12. ECOLOGICAL INFORMATION

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

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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.
	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

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):

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications WHMIS hazard class: Class B, Division 2 Class D, Division 2, Subdivision B



Isopropyl alcohol CERCLA/SARA 313 Emission reporting California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List

1.0 % Not Listed Present Present 200-661-7

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15. REGULATORY INFORMATION

Clindamycin Phosphate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	246-433-0
Propylene glycol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0
Water, purified	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness Flammable liquids-Cat.3; H225 - Highly flammable liquid and vapor Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Xn - Harmful Xi - Irritant F - Highly flammable

R11 - Highly flammable. R22 - Harmful if swallowed.

R22 - Harritoting to even

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.
	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
	Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the
	Company/Undertaking. Updated Section 16 - Other Information. Updated Section 7 - Handling
	and Storage. Updated Section 11 - Toxicology Information.

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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