



SAFETY DATA SHEET

Revision date: 31-Jul-2018

Version: 3.1

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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 T

Chemical 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

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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

Label Elements

Signal Word: Warning

Hazard Statements:
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 must 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

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

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	GHS Classification	%
Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	50
Clindamycin Phosphate	24729-96-2	246-433-0	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	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS 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.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including 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. Cleanup 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/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:	25 mg/L
Greece OEL - TWA	400 ppm
	980 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Russia OEL - TWA	10 mg/m ³
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
Switzerland OEL - TWAs	200 ppm
	500 mg/m ³

Clindamycin Phosphate
Pfizer OEL TWA-8 Hr: 100µg/m³

Propylene glycol
Australia TWA 150 ppm
474 mg/m³
10 mg/m³

Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³

Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

Exposure Controls

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Colorless
Odor:	Characteristic alcohol odor	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	

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.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
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

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
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.

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10. STABILITY AND REACTIVITY

Hazardous Decomposition 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.

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

Rat	Oral	LD 50	1832 mg/kg
Rat	Para-periosteal	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	3600 mg/kg
Rat	Inhalation	LC50-8h	16,000 ppm
Rabbit	Dermal	LD50	12800 mg/kg
Rat	Inhalation	LC50	30mg/L

Propylene glycol

Rat	Oral	LD 50	22,000 mg/kg
Mouse	Oral	LD 50	24,900mg/kg
Rabbit	Dermal	LD 50	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

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11. TOXICOLOGICAL INFORMATION

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

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)

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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

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.
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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

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

Isopropyl alcohol

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15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7

Clindamycin Phosphate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	246-433-0

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

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

16. OTHER INFORMATION

Text of CLP/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

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 31-Jul-2018

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.

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End of Safety Data Sheet