



SAFETY DATA SHEET

Revision date: 12-May-2015

Version: 3.0

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

Product Identifier

Material Name: Clindamycin Topical Solution (Greenstone LLC)

Trade Name: Not applicable
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

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

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

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

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: 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:

- P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
- P363 - Wash contaminated clothing before reuse
- 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
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water



Other Hazards
Australian Hazard Classification (NOHSC):

No data available
Hazardous Substance. Dangerous Goods.

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	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: * 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 R phrases and 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 fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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6. ACCIDENTAL RELEASE MEASURES

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

Environmental Precautions

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/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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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/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

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).

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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	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 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. May be harmful if swallowed.

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.

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

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

WHMIS hazard class:

Class B, Division 2

Class D, Division 2, Subdivision B



Isopropyl alcohol

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 R phrases and GHS Classification abbreviations mentioned in Section 3

H336 - May cause drowsiness and dizziness

Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; 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

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Xn - Harmful
Xi - Irritant
F - Highly flammable

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: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

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.

Revision date: 12-May-2015
Product Stewardship Hazard Communication

Prepared by: Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a 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