

EMERGENCY OVERVIEW

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.

Section 1. Identification

Product Name: Clindamycin gel

Formula: C₁₈H₃₄ClN₂O₈

Chemical Name: 2S-trans)-Methyl-7-chloro-6, 7, 8-trideoxy-6-[[[(1-methyl-4-propyl-2-yrrolidiny)carbonyl]-amino]-1-thio-L-threo-alpha-D-galacto-octopyranoside.

Molecular Weight: Mixture

Use: Active pharmaceutical ingredient (drug substance) for human use

Manufacturer / supplier identification

Company Zydus Lifesciences Ltd. Changodar, Ahmedabad. India

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Section 2. Hazard(s) Identification

Classification of the Substance or Mixture: Skin Sensitization: Category 1

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Label Elements Signal Word: Warning

Hazard Statements: H317 - May cause an allergic skin reaction

Precautionary Statements: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P271 - Use only outdoors or in a well-ventilated area

P280 - Wear protective gloves/protective clothing/eye protection/face protection

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).

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Section 3. Composition / information on ingredients

Clindamycin Phosphate - GHS Classification : Acute Tox.4 (H302), Eye Irrit.2A (H319), Skin Irrit.3 (H316), Skin Sens.1 (H317)

Additional Information: Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 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. Flush area with large amounts of water. Use soap. Seek medical attention.

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

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Section 5. Fire -fighting measures

Suitable Extinguishing Media: ABC

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

Special Hazards Arising from the Substance or Mixture

Products:

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

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 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

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:

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.

Personal Precautions: Use personal protective equipment

Section 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. Pharmaceutical drug product

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Section 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.

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.)

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.)

Section 9. Physical and chemical properties

Physical state:	Gel
Color:	Clear
Solubility:	Partially soluble
Melting Point:	NA

Section 10. Stability and Reactivity

Reactivity: No data available

Chemical Stability:

Stable at normal Conditions

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions

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NDC 72578-118-01 in tube of 30 g

NDC 72578-118-02 in tube of 60 g

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Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Section 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: Active ingredient may be harmful if swallowed. May cause eye irritation. May cause mild skin irritation (based on animal data).

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: 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

Section 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.

Section 13. Disposal Consideration

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.

Section 14. Transport Information

ADR/RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

Section 15. Regulatory Information

Allantoin

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: 202-592-8

Carbomer

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List Not Listed

Clindamycin Phosphate

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

EU EINECS/ELINCS List 246-433-0

Methylparaben

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

Inventory - United States TSCA - Sect. 8(b) Present

EU EINECS/ELINCS List 202-785-7

Polyethylene glycol 400

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65 Not Listed

Inventory - United States TSCA - Sect. 8(b) Present

Standard for the Uniform Scheduling Schedule 2

EU EINECS/ELINCS List Not Listed

Water, purify

CERCLA/SARA 313 Emission reporting Not Listed

California Proposition 65

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

CERCLA/SARA 313 Emission reporting Not Listed

EU EINECS/ELINCS List 231-791-2

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Section 16. Other information

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation

Date of issue: 21/09/23

Supersedes Edition: NA

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.