

PRODUCT: CLINDAMYCIN HYDROCHLORIDE CAPSULES USP	SDS NO. : SDS/GHS/GPL/401.00 EFFECTIVE DATE : 17/06/2022 PAGE No. : 1 of 15
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Section 1. Identification

1.1 Product Name: Clindamycin Hydrochloride Capsules USP

1.2 Synonyms: Not Known

1.3 Recommended use of the chemical and restrictions on use:
Antibacterial

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive
Mahwah, NJ 07430

1.5 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Skin Sensitization: Category 1,
Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Specific
Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3

2.2 Label elements:



Signal word	Warning
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2.3 Hazard statement:

H317	May cause an allergic skin reaction
H335	May cause respiratory irritation
H319	Causes serious eye irritation

2.4 Precautionary statement:

P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P103	Read label before use.



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Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.5 Other hazards: Not Known

Section 3- Composition/Information on Ingredients

3.1 Mixture:

CHEMICAL NAME	CAS #	%
Clindamycin Hydrochloride	21462-39-5	Proprietary
Magnesium stearate	557-04-0	Proprietary
Ingredients determined not to be hazardous [Mfr]	-	Proprietary

Section 4. First aid Measures

4.1 Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

4.2 Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

4.3 Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

4.4 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

4.5 Most important symptoms and effects, both acute and delayed
Treat symptomatically.

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Section 5. Fire-fighting Measures

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

5.2 Fire Incompatibility: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

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

5.4 Fire/Explosion Hazard: Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, sulphur, and chlorine.

Section 6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures:

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

6.2 Minor Spills: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

6.3 Major Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel. Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

Section 7. Handling and Storage

7.1 Safe Handling:

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. 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

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atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

7.2 Other Information (Storage):

Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

Bottles: Preserve in tight containers

Store as directed by product packaging

7.3 Suitable Container: Bottles Pack

7.4 Storage Incompatibility:

- Avoid strong acids, bases.
- Avoid reaction with oxidising agents

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
US OSHA Permissible Exposure Limits (PELs) Table Z-3	magnesium stearate	Inert or Nuisance Dust: Respirable fraction	5 mg/m ³ / 15 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-3	magnesium stearate	Inert or Nuisance Dust: Total Dust	15 mg/m ³ / 50 mppcf	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs) Table Z-1	magnesium stearate	Particulates Not Otherwise Regulated (PNOR)- Total dust	15 mg/m ³	Not Available	Not Available	Not Available
US OSHA Permissible Exposure Limits (PELs)	magnesium stearate	Particulates Not Otherwise Regulated (PNOR)-	5 mg/m ³	Not Available	Not Available	Not Available



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Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Table Z-1		Respirable fraction				
US NIOSH Recommended Exposure Limits (RELs)	magnesium stearate	Particulates not otherwise regulated	Not Available	Not Available	Not Available	See Appendix D

Ingredient	TEEL-1	TEEL-2	TEEL-3
clindamycin hydrochloride	Not Available	Not Available	Not Available
magnesium stearate	Not Available	Not Available	Not Available
Ingredient	Original IDLH		Revised IDLH
clindamycin hydrochloride	Not Available		Not Available
magnesium stearate	Not Available		Not Available

OCCUPATIONAL EXPOSURE BANDING

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
clindamycin hydrochloride	4	$\leq 0.01 \text{ mg/m}^3$
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.	

8.2 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.)

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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

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	Capsule
Colour	:	Opaque green
pH Value	:	Between 3.0 to 5.5
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Between 141 ⁰ C to 143 ⁰ C
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Soluble
Solubility in other solvents	:	Soluble in dimethylformamide, methanol, alcohol and insoluble in acetone
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known



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Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Not Known

10.2 Chemical Stability: Stable under normal conditions of use.

10.3 Possibility of hazardous reactions:

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

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

10.6 Hazardous Decomposition Products: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen chloride, phosgene, nitrogen oxides (NO_x), sulfur oxides (SO_x)
other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.

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Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled	Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.
Ingestion	Side-effects include severe and persistent diarrhoea, nausea, vomiting, abdominal cramps, possible passage of blood and mucous and abnormal taste. Colitis and diarrhoea may occur during or after treatment. Fatal pseudo-membranous colitis may also occur. Accidental ingestion of the material may be damaging to the health of the individual.
Skin Contact	Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. The material may accentuate any pre-existing dermatitis condition

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	Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	Hypersensitivity may also produce leucopenia, eosinophilia, liver damage and jaundice Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e. super- infection). Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agent and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile. Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray. Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur. An individual may be predisposed to such antibody mediated reaction if other chemical agents have caused prior sensitisation (cross-sensitivity).

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clindamycin hydrochloride	TOXICITY	IRRITATION
	Oral (Rat) LD50; 2193 mg/kg ^[2]	Not Available
magnesium stearate	TOXICITY	IRRITATION
	Oral (Rat) LD50; >10000 mg/kg ^[2]	Not Available
Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances		

Section 12. Ecological Information

12.1 Toxicity:

clindamycin hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
magnesium stearate	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data					

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability:

Ingredient	Persistence: Water/Soil	Persistence: Air
clindamycin hydrochloride	No Data available	No Data available



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Ingredient	Persistence: Water/Soil	Persistence: Air
magnesium stearate	No Data available	No Data available

12.3 Bio accumulative potential:

Ingredient	Bioaccumulation
clindamycin hydrochloride	No Data available
magnesium stearate	No Data available

12.4 Mobility in soil:

Ingredient	Mobility
clindamycin hydrochloride	No Data available
magnesium stearate	No Data available

Section 13. Disposal Considerations

13.1 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

Labels Required

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

**CLINDAMYCIN HYDROCHLORIDE IS FOUND ON THE FOLLOWING
REGULATORY LISTS**

- Not Applicable

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SECTION 311/312 HAZARD CATEGORIES

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	No



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Aspiration Hazard No

Germ cell mutagenicity No

Simple Asphyxiant No

Hazards Not Otherwise Classified No

US. EPA CERCLA HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES (40 CFR 302.4)

None Reported

State Regulations

US. CALIFORNIA PROPOSITION 65

None Reported

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (clindamycin hydrochloride)
Canada - DSL	Yes
Canada - NDSL	No (clindamycin hydrochloride)
China - IECSC	No (clindamycin hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	No (clindamycin hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	No (clindamycin hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	No (clindamycin hydrochloride)
Vietnam - NCI	Yes
Russia - FBEPH	No (clindamycin hydrochloride)
Legend:	Yes = All CAS declared ingredients are on the inventory



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National Inventory

Status

No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

Clindamycin Hydrochloride
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
EU EINECS/ELINCS List 244-398-6

Magnesium stearate
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 209-150-3

Section 16. Additional Information

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

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OSF: Odour Safety Factor

NOAEL: No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit of Detection

OTV: Odour Threshold Value

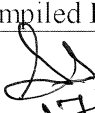
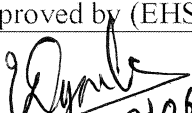
BCF: Bio Concentration Factors

BEI: Biological Exposure Index

NFPA: National Fire Protection Association

LDLo: Lethal dose low

TDLo: Toxic dose low

Compiled By (R & D)	Approved by (EHS Head)
 17/06/2022	 17/06/2022
Signature /Date	Signature /Date