

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078936138

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078940874 078940875 078940876



## SAFETY DATA SHEET – CLINDAMYCIN CAPSULES

### 1. IDENTIFICATION

Material Identification	:	Clindamycin Capsules 75mg, 150mg & 300mg			
Active ingredient	:	Methyl-7-chloro-6,7,8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrro-lidine carboxamido)-1-thio-L-threo--D-galacto-octopyranoside monohydrochloride monohydrate			
Molecular Formula	:	Mixture	Molecular Weight	:	Mixture
Active Ingredient	:	C <sub>18</sub> H <sub>33</sub> ClN <sub>2</sub> O <sub>5</sub> S.HCl.H <sub>2</sub> O	Active Ingredient	:	479.47
CAS Number	:	Mixture, N/A			
Product Use	:	Antibacterial			
Manufactured by	:	Micro Labs Limited Plot No: S-155 to S-159 & N1, Phase III & Phase IV, Verna Industrial Estate, Verna, Goa- 403722, India (IND) Tel : +91-832-2887142 Fax : +91-832-2887143	Manufactured for	:	Micro Labs USA Inc 106 Allen Road, Suite 102, Basking Ridge, NewJersey-07920, USA Tel:+1-908-484-7410
Emergency Contact	:	+91-9845496500			

### 2. HAZARDS IDENTIFICATION

Appearance	:	75mg – Green transparent body/green transparent cap 150mg- Green transparent body/ light blue opaque cap 300mg- Light blue opaque body/Light blue opaque cap
Statement of Hazard	:	May cause allergic reaction May cause eye irritation
Additional Hazard Information		
Short term	:	Active ingredient is not a skin irritant; Not acutely toxic (based on animal data).
Known Clinical Effects	:	Adverse effects associated with the therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Pseudomembranous colitis (manifested by watery diarrhoea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Material	CAS Number	%
Clindamycin Hydrochloride	21462-39-5	58.17
Lactose monohydrate	64044-51-5	*
Corn starch	9005-25-8	*
Talc	14807-96-6	*
Magnesium Stearate	557-04-0	*
Empty Hard gelatin capsule shell	Mixture	*

\* Proprietary

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

### 4. FIRST AID MEASURES

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

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing media</b>	:	Use carbon dioxide, dry chemical or water spray
<b>Hazardous combustion products</b>	:	Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, sulfur and chlorine.
<b>Fire /Explosion</b>	:	Not Applicable
<b>Hazards</b>		
<b>Fire Fighting Procedures</b>	:	During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.



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### 6. ACCIDENTAL RELEASE MEASURES

Health and safety Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for cleaning/collecting	:	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.
Measures of Environmental Protections	:	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.
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	:	Minimize dust generation and accumulation. If capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment.
Storage conditions	:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
Storage temperature	:	20 - 25°C (68-77°F)

### 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.
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#### Personal Protective Equipment

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.
Hands	:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eye Protection	:	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.



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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Hard gelatin Capsule
Appearance	:	75 mg - Green transparent body / Green transparent cap, size '3' hard gelatin capsules printed with 'M' on cap and '40' on body filled with white to off-white granular powder. 150mg - Green transparent body / Light blue opaque cap, size '2' hard gelatin capsule printed with 'M' on cap and '41' on body filled with white to off-white granular powder. 300mg- Light blue opaque body / Light blue opaque cap, size '0' hard gelatin capsule printed with 'M' on cap and '42' on body filled with white to off-white granular powder
Molecular Formula	:	Mixture
Molecular Weight	:	Mixture

### 10. STABILITY AND REACTIVITY

Stability	:	Stable under normal conditions of use.
Conditions to Avoid	:	None known.
Incompatible Materials	:	As a precautionary measure, keep away from strong oxidizers.

### 11. TOXICOLOGICAL INFORMATION

#### ROUTE OF EXPOSURE

Skin contact	:	Causes skin irritation
Skin absorption	:	May be harmful if absorbed through the skin
Eye contact	:	Causes eye irritation
Inhalation	:	Material is irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.
Ingestion	:	May be harmful if swallowed.

#### TARGET ORGAN(S) OR SYSTEM(S)

Nerves, kidneys, liver

#### SIGNS AND SYMPTOMS OF EXPOSURE

Aminoglycosides are associated with significant nephrotoxicity and/or ototoxicity.

#### TOXICITY DATA

##### Oral

Rat

2193 MG/KG

LD50

Remarks: Behavioural:Somnolence (general depressed activity)



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### **Intraperitoneal**

Rat

745 MG/KG

LD50

Remarks: Behavioural : Somnolence (general depressed activity)

### **Subcutaneous**

Rat

2618 MG/KG

LD50

Remarks: Behavioural: convulsions or effect on seizure threshold.

Behavioural: Somnolence (general depressed activity)

### **Intramuscular**

Rat

273 MG/KG

LD50

### **Oral**

Mouse

2539 MG/KG

LD50

Remarks: Behavioural: Somnolence (general depressed activity)

### **Intraperitoneal**

Mouse

361 MG/KG

LD50

### **Subcutaneous**

Mouse

1036 MG/KG

LD50

Remarks: Behavioural: Somnolence (general depressed activity)

Behavioural: Convulsions or effect on seizure threshold. Lungs, Thorax or Respiration: Dyspnea

### **Intravenous**

Mouse

245 MG/KG

LD50

Remarks: Behavioural : Somnolence (general depressed activity)

Behavioural: Convulsions or effect on seizure threshold.

### **Intramuscular**

Mouse

1100 MG/KG

LD50

Remarks: Behavioural: Altered sleep time (including change in righting reflex). Behavioural Somnolence (general depressed activity). Behavioural: Ataxia

### **CHRONIC EXPOSURE-CARCINOGEN**

Result: This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP or EPA classification.



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### 12. ECOLOGICAL INFORMATION

**Environmental Overview** : Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures** : Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

### 14. TRANSPORTATION INFORMATION

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

### 15. REGULATORY / STATUTORY INFORMATION

EU Indication of damage : Irritant  
EU Risk Phrases : R36- Irritating to eyes  
R43- May cause sensitization by skin contact  
EU Safety Phrases : S22- Do not breathe dust  
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S37- Wear suitable gloves.

**OSHA Label:**

May cause allergic reaction  
May cause eye irritation

**Canada-WHMIS:Classifications**

**WHMIS hazard class**

Class D, Division 2 and Subdivision B.

### 16. OTHER INFORMATION

Date of preparation: 13-Dec-2018

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific



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material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

Micro Labs Limited believes 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.

**End of Safety Data Sheet**