




# MATERIAL SAFETY DATA SHEET

## LINCOMYCIN INJECTION USP, 300MG/ML

### 1. IDENTIFICATION

<b>Material Identification</b>	:	Lincomycin Injection USP, 300mg/ml			
<b>Active ingredient</b>	:	Carbonyl]amino]-1-thio-D-erythro- $\alpha$ -D-galacto-octopyranoside(lincomycin) hydrochloride monohydrate			
<b>Molecular Formula</b>	:	C <sub>18</sub> H <sub>34</sub> N <sub>2</sub> O <sub>6</sub> S. HCL. H <sub>2</sub> O	<b>Molecular Weight</b>	:	461.01 g/mol
<b>CAS Number</b>	:	859-18-7			
<b>Product Use</b>	:	Antibiotic			
<b>Manufactured by</b>	:	<b>Micro Labs Limited</b> Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	<b>Manufactured for</b>	:	<b>Armas Pharmaceuticals Inc.</b> 303 West Main Street Suite 300 Freehold, NJ 07728
<b>Emergency Contact</b>	:	+91-80-27839033			

### 2. HAZARDS IDENTIFICATION

<b>Label Elements</b>		
<b>Signal</b>	:	Warning 
<b>Physical hazards</b>	:	
<b>Classification of the substance</b>	:	Not classified
<b>Hazard statements</b>	:	Non-hazardous in accordance with international standards for workplace safety. Can cause skin and eye irritation. Ingestion may produce abdominal pain and vomiting.
<b>Precautionary statements</b>	:	P260: Do not breathe dust/fume/gas/mist/vapors/spray P264: Wash face, hands and any exposed skin thoroughly after handling. P301+312: IF SWALLOWED: Call a POISON CENTER or doctor / physician if you feel unwell. P314: Get medical attention/advice if you feel unwell P330: Rinse mouth. P501: Dispose of contents/container in accordance with all local and national regulations
<b>Hazard(s) not otherwise classified (HNOC)</b>	:	None known



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS #	EINECS #	% w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
<b>Active Pharmaceutical Ingredient</b>				
Lincomycin Hydrochloride Carbonyl]amino]-1-thio-D-erythro- $\alpha$ -D-galactooctopyranoside(lincomycin) hydrochloride monohydrate	859-18-7	212-726-7	Proprietary	EU 67/548/EEC: Classification: Acute skin, eye, respiratory toxicity Category 1, 1A, 1B and 2 Risk Phrase Codes: R43 Hazard Symbols: Xi  GHS & EU 1272/2008: Classification: Skin corrosion/irritation: Category 2, skin sensitization: Category 1, 1A and 1B, serious eye damage/eye irritation: Category 2A, respiratory sensitization: Category 1, 1A and 1B, specific target organ toxicity, single exposure, respiratory tract irritation: Category 3 Hazard codes: H315, H317, H319, H334, H335 Hazard symbol/Pictogram: GHS07, GHS08
<b>Excipient</b>				
Benzyl Alcohol	100-51-6	202-859-9	Proprietary	EU 67/548/EEC: Classification: Acute oral toxicity Category 4 Risk Phrase Codes: R20, R22 Hazard Symbols: Xn  GHS & EU 1272/2008: Classification: Acute toxicity Category 4 oral, Acute toxicity Category 4 inhalation, Eye irritation Category 2, Hazard codes: H302, H332, H319 Hazard symbol/Pictogram: GHS07

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

### 4. FIRST AID MEASURES

Eyes Contact	:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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Skin Contact	:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. Delayed effects may occur. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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

Extinguishing media : Use carbon dioxide, dry chemical and water spray.

#### General Information

As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH approved or equivalent), and full protective gear. During a fire, carbon oxides, Nitrogen oxides, Hydrogen chloride gas may be generated.

### 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 labelled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods for cleaning up	:	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. Wash thoroughly after handling. 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.
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#### Conditions for safe storage, including any incompatibilities

Storage conditions : Store at controlled room temperature of 20°C-25°C (68°F-77°F).

Specific end use(s) : Pharmaceutical drug product for patients

### 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 occupational exposure limits, 100µg/m <sup>3</sup> .
Personal Protective Equipment	:	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.



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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 protection	:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Injection
Color	:	Clear, colorless to slightly yellowish solution. Practically free from visible particles.
Appearance	:	<b>Lincomycin Injection USP, 300mg/ml:</b> Clear, colorless solution, free from visible particles.
Molecular Formula	:	C <sub>18</sub> H <sub>34</sub> N <sub>2</sub> O <sub>6</sub> S. HCL. H <sub>2</sub> O
Molecular Weight	:	461.01 g/mol

### 10. STABILITY AND REACTIVITY

Reactivity	:	Stable under recommended storage conditions.
Conditions to Avoid	:	No data available
Incompatible Materials	:	No data available

### 11. TOXICOLOGICAL INFORMATION

Acute Toxicity	:	<b>Lincomycin Hydrochloride</b> Rat Oral LD 50 >4000 mg/kg Rat Para-periosteal LD 50 342 mg/kg Mouse Intravenous LD 50 214 mg/kg Rat Subcutaneous LD 50 9778 mg/kg  <b>Benzyl Alcohol</b> Rat Oral LD 50 1230 mg/kg Rat Para-periosteal LD 50 53 mg/kg Rat Inhalation LC 50 46 mg/m <sup>3</sup>
Skin Irritation/ Sensitization	:	<b>Benzyl Alcohol</b> Rabbit: Moderate Guinea Pig: Moderate
Eye irritation	:	Rabbit: Severe
Repeated dose toxicity	:	<b>Lincomycin Hydrochloride</b> 30 Day(s) Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose 30 Day(s) Rat Subcutaneous 60 mg/kg/day NOAEL None identified 3 Month(s) Rat Oral 300 mg/kg/day NOAEL None identified 3 Month(s) Dog Oral 400 mg/kg/day LOAEL None identified 6 Month(s) Dog Oral 100 mg/kg/day NOAEL Immune system



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Reproduction and Developmental toxicity	:	<b>Lincomycin Hydrochloride</b> 2 Generation Reproductive Toxicity Rat Oral 100 mg/kg LOAEL Fetotoxicity Prenatal & Postnatal Development Rat Oral 100 mg/kg NOEL Not Teratogenic Fertility and Embryonic Development Rat Subcutaneous 75 mg/kg/day NOAEL No effects at maximum dose Embryo / Fetal Development Rat Subcutaneous 300 mg/kg/day NOAEL Not Teratogenic Peri-/Postnatal Development Rat Subcutaneous 30 mg/kg/day NOAEL No effects at maximum dose
Genetic toxicity	:	<b>Lincomycin Hydrochloride</b> Bacterial Mutagenicity (Ames) <i>Salmonella</i> Negative Mammalian Cell Mutagenicity Mouse Lymphoma Negative <i>In Vivo</i> Micronucleus Rat Negative Direct DNA Interaction Human Lymphocytes Negative
Carcinogenicity	:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
IARC:	:	Not carcinogenic
NTP:	:	Not carcinogenic

### 12. ECOLOGICAL INFORMATION

General Notes	:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Aquatic toxicity:	:	<b>Lincomycin Hydrochloride</b> <i>Lepomis macrochirus</i> (Bluegill Sunfish) ASTM LC50 96 Hours >980 mg/L <i>Daphnia magna</i> (Water Flea) ASTM EC50 48 Hours >900 mg/L <i>Anabaena flos-aquae</i> (Cyanobacteria) OECD EC50 72 Hours 0.03 mg/L <i>Salmo gairdneri</i> (Trout) ASTM LC50 96 Hours >980 mg/L  A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.
Persistence and degradability	:	No data available
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available
Results of PBT and vPvB	:	data not 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. TRANSPORTATION INFORMATION

Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	No data available
Packing group	:	No data available
IATA UN number	:	No data available
Environmental hazards	:	No data available
Special precautions for user	:	No data available

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

### 15. REGULATORY / STATUTORY INFORMATION

Seveso regulation (Directive 96/82/EC)	:	Not Available
Candidate list (art. 59-REACH):	:	Not Available
Ozone depletion substance (2000/2037/EC)	:	Not Available
Import/export dangerous chemical (2008/689/EC)	:	Not Available

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

R20/22 - Harmful by inhalation and if swallowed.

Date of preparation: 20/03/23

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**End of Safety Data Sheet**