



Safety Data Sheet

# Lincomycin Hydrochloride Injection, USP

## Section 1: Chemical Product and Company Identification

**Product Name:** Lincomycin Hydrochloride Injection, USP

**Chemical Name(s):** Methyl 6, 8-dideoxy-6-(1-methyl-trans-4-propyl-L2-pyrrolidinecarboxamido)-1-thio-D-erythro- $\alpha$ -D-galacto-octopyranoside monohydrochloride monohydrate

**Synonym:** Lincomycin Hydrochloride Injection, USP

**CAS Number:** 859-18-7

**RTECS #:** Not available

**Trade Name:** Lincocin Injection

**Chemical Formula:**  $C_{18}H_{34}N_2O_6S \cdot HCl \cdot H_2O$



### Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

**Technical Assistance:** 607-562-2700

**Online Assistance:** [www.x-gen.us](http://www.x-gen.us)

### Emergency phone number:

National Poison Control

1-800-222-1222

Health	1
Fire	1
Reactivity	0
Personal Protection	E

\*\*For information regarding recommended uses and restrictions on usage refer to the product package insert.

## Section 2: Hazard Identification

### Hazard pictograms (GHS-US):



**Potential Acute Health Effects:** May cause eye, skin and respiratory tract irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

**Oral Cat:** Acute toxicity. 4; H302 - Harmful if swallowed

**Inhalation Cat:** Acute toxicity. 4; H332 - Harmful if inhaled

### Potential Chronic Health Effects:

**Skin Cat:** Sensitization. 1; H317 - May cause an allergic skin reaction

**Carcinogenic Effects:** Not available

**Mutagenic Effects:** Not available

**Teratogenic Effects:** Not available

**Developmental Toxicity:** Not available

**Adverse effects:** The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming organs have also occurred.

### Section 3: Composition and Information on Ingredients

#### Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Lincomycin Hydrochloride	859-18-7	0.5
Benzyl Alcohol	100-51-6	<5
Water for Injection	7732-18-5	Proprietary

### Section 4: First Aid Measures

**General:** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

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

**Skin contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Delayed effects may occur. For information on potential delayed effects, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information. Seek medical attention immediately.

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

**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.

**Notes to physician:** None.

**Overdose Treatment:** Not available.

### Section 5: Fire Fighting Measures

**Flammability of the product:** May be combustible at high temperatures.

**Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Unusual Fire and Explosion Hazards:** Fine particles (such as mists) may fuel fires/explosions.

**Extinguishing Media and instruction:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**Protective equipment & precautions for firefighters:** Wear appropriate protective equipment, including self-contained breathing apparatus.

**Special remarks on fire hazard:** Not available

**Special remarks on explosion hazard:** Not available

## Section 6: Accidental Release Measures

**Environmental Precautions:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Release to land:

**Small spill:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Large spill:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

**Release to air:** Not available

**Release to water:** Not available

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

## Section 7: Handling and Storage

**Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

**Storage:** Store in a cool, dry place away from light. Keep out of reach of children.

**Incompatibilities:** As a precautionary measure, keep away from strong oxidizers.

## 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 Protection:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**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.

**Exposure limit:** Not available

**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

## Section 9: Physical and Chemical Properties

**Physical state and appearance:** Liquid

**Color:** Colorless

**Molecular Weight:** Mixture

**Taste:** Not available

**Odor:** Not available

**Odor Threshold:** Not available

**pH:** 3.0 – 5.5

**Melting Point:** Not available

**Freezing Point:** Not available

**Boiling Point:** Not available

**Flash Point:** Not available

**Evaporation rate:** Not available

**Flammability:** May be combustible at high temperatures.

**Upper Flammable Limit:** Not available

**Lower Flammable Limit:** Not available

**Vapor Pressure:** Not applicable

**Vapor Density:** Not available

**Relative density:** Not available

**Partition Coefficient:** Not available

**Auto-Ignition Temperature:** Not available

**Decomposition Temperature:** Not available

**Viscosity:** Not available

**Dispersion Properties:** Not available

**Solubility:** Soluble in water

## Section 10: Stability and Reactivity

**Reactivity:** Not available

**Chemical stability:** Stable under normal conditions of use.

**Conditions to avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

**Incompatible materials:** As a precautionary measure, keep away from strong oxidizers.

**Possibility of Hazardous Reactions:** Not available

**Hazardous decomposition products:** Not available

**Corrosivity:** Non-corrosive in presence of glass.

**Polymerization:** May react with strong oxidizing agents (e.g. peroxides, permanganates, nitric acid, etc.).

## Section 11: Toxicological Information

**Routes of exposure:** Inhalation. Ingestion.

### Symptoms:

**Short term:** May cause eye, skin and respiratory tract irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

**Reproductive toxicity:** Not available

**FDA Pregnancy Category:** C

**Known Clinical Effects:** The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Effects on blood and blood-forming organs have also occurred. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

**Acute Toxicity: (Species, Route, End Point, Dose)**

### Lincomycin Hydrochloride

**Oral Rat:** LD 50 >4000 mg/kg

**Para-periosteal Rat:** LD 50 342 mg/kg

**Intravenous Mouse:** LD 50 214 mg/kg

**Subcutaneous Rat:** LD 50 9778 mg/kg

### Benzyl Alcohol

**Oral Rat:** LD 50 >1230 mg/kg

**Para-periosteal Rat:** LD 50 53 mg/kg

**Inhalation Rat:** LD 50 74.178 mg/L

### 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)**

**Benzyl Alcohol**

**Rabbit:** Eye Irritation Severe

**Rabbit:** Skin Irritation Minimal

**Guinea Pig:** Skin Irritation Moderate

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Lincomycin Hydrochloride**

**Oral Rat:** 30 Day(s) 300 mg/kg/day NOAEL No effects at maximum dose

**Subcutaneous Rat:** 30 Day(s) 60 mg/kg/day NOAEL None identified

**Oral Rat:** 3 Month(s) 300 mg/kg/day NOAEL None identified

**Oral Dog:** 3 Month(s) 400 mg/kg/day LOAEL None identified

**Oral Dog:** 3 Month(s) 100 mg/kg/day NOAEL Immune system

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Lincomycin Hydrochloride**

**Oral Rat:** 2 Generation Reproductive Toxicity 100 mg/kg LOAEL Fetotoxicity

**Oral Rat:** Prenatal & Postnatal Development 100 mg/kg NOAEL Not Teratogenic

**Subcutaneous Rat:** Fertility and Embryonic Development 75 mg/kg/day NOAEL No effects at maximum dose

**Subcutaneous Rat:** Embryo / Fetal Development 300 mg/kg/day NOAEL Not Teratogenic

**Subcutaneous Rat:** Peri- / Postnatal Development 30 mg/kg/day NOAEL No effects at maximum dose

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Lincomycin Hydrochloride**

**Salmonella:** Bacterial Mutagenicity (Ames) Negative

**Mouse Lymphoma:** Mammalian Cell Mutagenicity Negative

**Rat:** In Vivo Micronucleus Negative

**Human Lymphocytes:** Direct DNA Interaction Negative

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**Section 12: Ecological Information**

**Ecotoxicity:** Not available

**Bioaccumulation potential:** Not available

**Products of biodegradation:** Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

**Toxicity of the products of biodegradation:** The products of degradation are more toxic.

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

**Toxicity: Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Lincomycin Hydrochloride**

Lepomis macrochirus (Bluegill Sunfish)	ASTM LC50	96 Hours	>980mg/L
Daphnia magna (Water Flea)	ASTM EC50	48 Hours	>900mg/L
Anabaena flos-aquae (Cyanobacteria)	OECD EC50	72 Hours	0.03mg/L
Salmo gairdneri (Trout)	ASTM LC50	96 Hours	>980mg/L

**Benzyl Alcohol**

Pimephales promelas (Fathead Minnow)	EPA LC50	96 Hours	460mg/L
Daphnia magna (Water Flea)	OECD EC50	48 Hours	230mg/L
Pseudokirchneriella subcapitata (Green Alga)	OECD EC50	72 Hours	500mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

**Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)**

**Benzyl Alcohol**

Daphnia magna (Water Flea)	OECD	21 Day(s)	EC50 66 mg/L	Reproduction
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**Persistence and Degradability**

**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

**Benzyl Alcohol**

OECD Activated sludge	Ready	92% after	14Day(s)	Read
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**Bio-accumulative Potential**

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Lincomycin Hydrochloride**

Measured	6-8	Log D	2.55
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**Section 13: Disposal Information**

**Waste Classification:** Hazardous

**Waste from residues/unused products:** Dispose of waste in accordance with all applicable federal, state and local laws.

**Waste Disposal:** Dispose of waste in accordance with all applicable federal, state and local laws.

**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

**DOT Classification:** Not a DOT controlled material (United States).

**UN Number:** Not available

**UN Shipping name:** Not available

**Transport hazard class:** Not available

**Packing Group:** Not available

**Environmental hazard:** Not available

**Transport in bulk:** Not available

**Special precautions needed with transport:** Not available

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

## Section 15: Regulatory Information

**Federal and State Regulations:** No products were found.

**Other Regulations:** Not available

**Other Classifications:**

**WHMIS (Canada):** Not controlled under WHMIS (Canada).

**DSCL (EEC):** This product is not classified according to the EU regulations. Not applicable.

**Lincomycin Hydrochloride**

CERCLA/SARA 313 Emission reporting: Not available

California Proposition 65: Not available

Australia (AICS): Present

EU EINECS/ELINCS List 212-726-7

**Water**

CERCLA/SARA 313 Emission reporting: Not available

California Proposition 65: Not available

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

**Benzyl Alcohol**

CERCLA/SARA 313 Emission reporting: Not available

California Proposition 65: Not available

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

Australia (AICS): Present

EU EINECS/ELINCS List 202-859-9



**HMIS (U.S.A.):**  
**Health Hazard:** 1  
**Fire Hazard:** 1  
**Reactivity:** 0  
**Personal Protection:** E

**National Fire Protection Association (U.S.A.): Health:** 1  
**Flammability:** 1  
**Reactivity:** 0

**Protective Equipment:** Gloves, lab coat, Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

**Section 16: Other Information**

**References:** Not available

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**Last Updated:** 1/13/2016

**Prepared & Approved by:** X-GEN Pharmaceuticals, Inc., Quality Assurance & Safety Committee

*The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.*