

SAFETY DATA SHEET

Issue Date: 09/30/2024

Revision Date: N/A

Revision Number: 01

1. IDENTIFICATION

Product identifier: Lincomycin Hydrochloride Injection, USP (NDC: 0121-1035-55)

Distributor Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – antibiotic

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitization Category 1

Label Elements:

Hazard statement(s)

May cause an allergic skin reaction.



Precautionary statement(s)

IF on skin: wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.

Precautionary statement(s)

Avoid breathing mists.
Contaminated clothing must not be allowed out of the workplace.
Wear protective clothing and gloves.

Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Lincomycin Hydrochloride	859-18-7	0.5%
Benzyl Alcohol	100-51-6	1-5
Water	7732-18-5	Balance

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or symptoms occur, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation persists or rash occurs, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation or symptoms persist.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing may cause nausea, vomiting, diarrhea, abdominal pain, itching. Inhalation of mists may cause respiratory irritation and symptoms similar to ingestion. May cause allergic skin reaction.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Lincomycin Hydrochloride	None Established
Benzyl Alcohol	10 ppm TWA AIHA&OARS WEEL
Water	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded or if irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Pink solution.

Odor: Raspberry

Physical State: Liquid	Color: No data available
Odor: No data available	pH: No data available
Melting point/freezing point: No data available	Boiling Point: No data available
Flash point: No data available	Evaporation rate: No data available
Flammability: Not applicable	VOC: No data available
Flammable limits: LEL: No data available	UEL: No data available
Vapor pressure: No data available	Relative vapor density: No data available
Relative density: No data available	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: No data available	Auto-ignition temperature: No data available
Decomposition temperature: No data available	Kinematic Viscosity: No data available
Particle Characteristics: Not applicable	

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides and chlorine compounds.

11. TOXICOLOGICAL INFORMATION**Acute effects of exposure:**

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.

Ingestion: . Swallowing may cause nausea, vomiting, diarrhea, abdominal pain, itching.

Skin contact: May cause mild irritation. May cause an allergic skin reaction.

Eye contact: May cause mild irritation.

Chronic Effects: None known.

Sensitization: Lincomycin hydrochloride is a skin sensitizer.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens. Lincomycin was not found to be mutagenic in the Ames *Salmonella* reversion assay or the V79 Chinese hamster lung cells at the HGPRT locus. It did not induce DNA strand breaks in V79 Chinese hamster lung cells as measured by alkaline elution or chromosomal abnormalities in cultured human lymphocytes. *In vivo*, lincomycin was negative in both the rat and mouse micronucleus assays and it did not induce sex-linked recessive lethal mutations in the offspring of male *Drosophila*. However, lincomycin did cause unscheduled DNA syntheses in freshly isolated rat hepatocytes.

Reproductive Toxicity: Components are not classified as reproductive toxins. Impairment of fertility was not observed in male or female rats given oral 300 mg/kg doses of lincomycin. There was no evidence of teratogenicity when lincomycin was administered in diet to pregnant Sprague Dawley rats during the period of major organogenesis at doses up to 5000 mg/kg. Reproduction studies performed in rats administered oral lincomycin in diet for 2 weeks prior to mating, throughout pregnancy and lactation, revealed no adverse effects on survival of offspring from birth to weaning at doses up to 1000 mg/kg.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 3125 mg/kg

Lincomycin Hydrochloride: Oral rat LD50 >4000 mg/kg

Benzyl Alcohol: Oral rat LD50 1620 mg/kg; LC50 inhalation rat >4.178 mg/L/4h

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: N/A

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.