SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: LINCOCIN® INJECTION
SYNONYMS: LINCOCIN® Sterile Solution, 474001 - EDP Number, lincomycin hydrochloride injection, USP, 0009-0555-01 - NDC NUMBER, 0009-0555-02 - NDC NUMBER
USE: Human drug used in the treatment of serious bacterial infections due to susceptible strains of streptococci, pneumococci and staphy lococci.
MANUFACTURER: PHARMACIA & UPJOHN, 7171 Portage Road, Kalamazoo, MI 49001-0199
DATA SOURCE: PHARMACIA & UPJOHN, 7171 Portage Road, Kalamazoo, MI 49001-0199
TELEPHONE NUMBERS: (616) 833-5122 (24 Hours), (616) 833-7555 (8:00 a.m. - 4:30 p.m.)

SECTION 2 - COMPOSITION / INFORMATION ON INGREDIENTS

INGREDIENT 1
COMMON NAME: Water
% BY WEIGHT: < 70%
CAS NUMBER: 7732-18-5
EXPOSURE LIMIT (S): Not established.

INGREDIENT 2
COMMON NAME: Lincomycin Hydrochloride
% BY WEIGHT: 30%
CAS NUMBER: 859-18-7
EXPOSURE LIMIT (S):
PHARMACIA & UPJOHN EXPOSURE LIMIT-TWA: 0.1 mg/m^3

INGREDIENT 3
COMMON NAME: Non-hazardous Ingredient (s)
% BY WEIGHT: < 1%
EXPOSURE LIMIT (S): Not established.

EXPOSURE LIMIT (S) FOR THE MATERIAL: Not established.
The MSDS for the active ingredient may be referred to for additional information on handling the bulk product.
SECTION 3 - HAZARDS IDENTIFICATION

PRIMARY ROUTE (S) OF EXPOSURE: Skin contact, eye contact, ingestion and inhalation. EFFECTS OF OVEREXPOSURE: This product is not acutely toxic, but may cause irritation to the eyes, skin and respiratory passages. Repeated exposure may cause nausea, abdominal cramps, diarrhea and colitis which may begin several weeks after exposure has ceased. Some hematopoietic effects have been reported with the use of lincomycin hydrochloride. Hypersensitivity reactions have been reported in people known to be sensitive to penicillin. MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Exposure to Lincozin is contraindicated in people with a history of hypersensitivity to lincomycin, clindamycin or related antibiotics, a history of asthma or significant allergies or a history of gastrointestinal disease (especially colitis).

SECTION 4 - FIRST AID MEASURES

EYES: Flush with water for 15 minutes. Hold eyelids open to assure complete contact with water.
SKIN: Wash with soap and water. Remove contaminated clothing.
INHALATION: Remove from exposure.
INGESTION: Contact a physician or poison control center.

SECTION 5 - FIRE FIGHTING MEASURES

FLASH POINT: Nonflammable
LOWER EXPLOSION LIMIT (LEL): Not applicable.
UPPER EXPLOSION LIMIT (UEL): Not applicable.
EXTINGUISHING MEDIA: Water Carbon dioxide, or dry chemical.
FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full body protective equipment.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep product out of drains; prevent entry to surface water, groundwater and soil. Small spills should be absorbed with paper towel or other appropriate media. Large spills can be vacuumed or scooped and placed in a suitable container.
SECTION 7 - HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothes before reuse. Store in a cool, dry place and protect from light. Keep out of the reach of children.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required.
VENTILATION: Local exhaust.
PROTECTIVE GLOVES: Not required.
EYE PROTECTION: Not required.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE / PHYSICAL STATE: Liquid (300 mg/ml) in 2 ml and 10 ml vials.
MOLECULAR WEIGHT: Mixture
SOLUBILITY IN WATER: Freely soluble.

SECTION 10 - STABILITY AND REACTIVITY

STABILITY: Stable
PHYSICAL CONDITIONS TO AVOID: None
INCOMPATIBILITY WITH OTHER MATERIALS: None
HAZARDOUS DECOMPOSITION PRODUCTS: None
HAZARDOUS POLYMERIZATION: Does not occur.

SECTION 11 - TOXICOLOGICAL INFORMATION

ACUTE STUDIES:
SENSITIZATION: Hypersensitivity reactions to lincomycin hydrochloride have been reported. These reactions were characterized by angioneurotic edema, serum sickness and anaphylaxis and occurred occasionally to people known to be sensitive to penicillin. Rare instances of erythema multiforme, sometimes resembling Stevens-Johnson syndrome, have been associated with lincomycin hydrochloride.
ORAL LD50 (RAT): 15,645 mg/kg.
INTRAPERITONEAL LD50 (MOUSE): 1,000 mg/kg.
CHRONIC STUDIES: No evidence was obtained that Lincozin (when given in sustained parenteral dosages of 50 mg/kg/day to pregnant females) produced a teratogenic effect on the canine embryo.
OTHER STUDIES:
GENOTOXICITY: Mutagenicity: Many tests (including the Ames, Chinese hamster V-79 cell, DNA/alkaline elution, rat primary hepatocytes - unscheduled DNA repair and the in vitro human lymphocytes tests) were all negative when tested against lincomycin hydrochloride.  
CARCINOGENICITY: Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

SECTION 12 ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE:
MOBILITY: Lincomycin hydrochloride melts with decomposition at 148°C. It has no measurable vapor pressure, therefore it is not expected to enter the air. Lincomycin hydrochloride is very soluble in water (500 - 1000 mg/ml) and undergoes hydrolysis at both acid and basic pHs is elevated temperatures. Lincomycin can be sorbed to soil, but it is readily leached away from soils, and so, is expected to be relatively mobile and migrate toward the aquatic compartment.
PERSISTENCE / DEGRADABILITY: Lincomycin hydrochloride can undergo hydrolysis at both acid and basic pHs at elevated temperatures; in the pH range 3 to 6 at room temperature, degradation is small. Lincomycin bioactivity is readily degraded by mixtures of urine, feces and soil. The half-life of degradation was about 20 days.
BIOACCUMULATIVE POTENTIAL: Lincomycin has a low octanol-water partition coefficient at all pHs. The octanol-water partition at pH 7 is 2.55. Calculated flowing the static bioaccumulation factors are 2.21 and 9.96 respectively. Lincomycin will be expected to migrate to the aqueous environment, but it should not bioaccumulate in aquatic organisms.
ABIOTIC POTENTIAL: Lincomycin hydrochloride will have some initial inhibitory effects on the most sensitive microorganisms until it is degraded. Small amounts sent to sanitary sewage will not adversely affect the abiotic flora of sewage treatment facilities.
ECOTOXICITY: No adverse effect, 96 hour in rainbow trout: 980 mg/l; no adverse effect, 96 hour in bluegill: 980 mg/l; no adverse effect, 48 hour in Daphnia magna: >900 mg/l.

SECTION 13 - DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable international, national, state, and/or local waste disposal regulations.

SECTION 14 - SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

SECTION 15 - OTHER INFORMATION

REVIEWED BY: Environment and safety.
DISCLAIMER: The information contained in the MSDS is believed to be correct as of its date of issuance. BY MAKING THE MSDS AVAILABLE, PHARMACIA & UPJOHN DOES NOT MAKE ANY EXPRESS OR IMPLIED WARRANTY (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) REGARDING THE MSDS. ITS ACCURACY OR THE PRODUCT TO WHICH IT RELATES. Anyone using this information agrees that Pharmacia & Upjohn shall not be held liable (based on its negligence or otherwise) for any personal injury or other damage relating to, or arising from such use, including direct, incidental, or consequential damage and such user agrees to indemnify Pharmacia & Upjohn for any claims arising out of its use.

SECTION 16 - LABELING

This drug is subject to FDA labeling requirements; therefore, it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.

Revision Date: November 21, 1995