

**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**COMMON NAME:** CLEOCIN® Vaginal Cream  
**USE:** Human drug used in the treatment of bacterial vaginosis.

**MANUFACTURER/SUPPLIER:**  
THE UPJOHN COMPANY  
7171 PORTAGE RD.  
KALAMAZOO, MI 49001-0199

**TELEPHONE NUMBERS:**  
(616) 323-5122 (24 Hours)  
(616) 323-7555 (8:00 AM - 4:30 PM)

**2. COMPOSITION/INFORMATION ON INGREDIENTS****INGREDIENT 1**

**COMMON NAME:** Water.  
**% BY WEIGHT:** 73% (approximate)  
**CAS NUMBER:** 7732-18-5  
**EXPOSURE LIMIT(S):** Not established.

**INGREDIENT 2**

**COMMON NAME:** Non-hazardous Ingredient(s).  
**% BY WEIGHT:** 25% (approximate)  
**EXPOSURE LIMIT(S):** Not established.

**INGREDIENT 3**

**COMMON NAME:** Clindamycin Phosphate.  
**CHEMICAL NAME:** L-threo- $\alpha$ -D-galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[(1-methyl-4-propyl-2-pyrrolidinyl)-carbonyl]amino]-1-thio-, 2-(dihydrogen phosphate), (2S-trans)-  
**% BY WEIGHT:** 2% (active ingredient)  
**CAS NUMBER:** 24729-96-2  
**EXPOSURE LIMIT(S):**  
UPJOHN EXPOSURE LIMIT-TWA: 0.1 mg/m<sup>3</sup>

**EXPOSURE LIMIT(S) FOR THE MATERIAL:**  
Not established.

**3. HAZARDS IDENTIFICATION**

**PRIMARY ROUTE(S) OF EXPOSURE:** Skin contact, eye contact, ingestion and inhalation.  
**EFFECTS OF OVEREXPOSURE:** Overexposure to the active ingredient, clindamycin phosphate, may cause gastrointestinal effects including: nausea, vomiting, diarrhea, abdominal pain, passage of mucous and blood in the stools. In addition, pseudomembranous colitis and esophagitis have occurred. Severe colitis may be fatal. Other less frequent adverse effects include: hypersensitivity reactions characterized by skin rash, redness and itching; neutropenia evidenced by sore throat and fever; thrombocytopenia indicated by unusual bleeding or bruising; jaundice and abnormalities in liver function tests and renal dysfunction (although there has been no direct relationship established between clindamycin and renal damage). Rare cases of polyarthritis have been reported with the use of clindamycin phosphate. Irritation to the eyes, skin and respiratory passages may occur.

**MEDICAL CONDITIONS AGGRAVATED BY**

**EXPOSURE:** Exposure in contraindicated in people with a history of hypersensitivity to clindamycin,

**3. HAZARDS IDENTIFICATION, Con't**

lincomycin or other related families of antibiotics, a history of regional enteritis or ulcerative colitis, antibiotic-associated colitis, individuals with atopy, chronic respiratory or skin disease.

**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.

**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 OR EXPLOSION HAZARDS:** None.

**HAZARDOUS COMBUSTION PRODUCTS:** Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulfur oxides.

**6. ACCIDENTAL RELEASE MEASURES**

**STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:** Small amounts of the product can be diluted with alcohol and wiped up. Provide ventilation and respiratory, skin and eye protection to prevent overexposure. Keep the product out of drains; prevent entry to surface water, groundwater and soil. Small spills should be absorbed with paper towels or other appropriate media. Large spills can be vacuumed or scooped and placed in a suitable container.

**7. HANDLING AND STORAGE****PRECAUTIONS FOR HANDLING AND STORING:**

Avoid contact with skin, eyes and clothing. Wash thoroughly after handling. Launder contaminated clothing before reuse. Store in a cool, dry place. Keep out of the reach of children.

**8. EXPOSURE CONTROLS/ PERSONAL PROTECTION**

**RESPIRATORY PROTECTION:** Not required.

**VENTILATION:** Local exhaust.

**PROTECTIVE GLOVES:** Not required.

**EYE PROTECTION:** Not required.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**APPEARANCE/PHYSICAL STATE:** Cream in 40-g tube.

**MOLECULAR WEIGHT:** Mixture.

**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.

**11. TOXICOLOGICAL INFORMATION****ACUTE STUDIES:**

**EYE IRRITATION (RABBIT):** Moderately irritating and damaging (clindamycin phosphate).

**SKIN IRRITATION (RABBIT):** Mildly irritating to abraded skin (clindamycin phosphate).

**SENSITIZATION:** Hypersensitivity reactions may occur with the use of clindamycin phosphate that include: morbilliform-like rash, maculopapular rash, urticaria, pruritis, fever, hypotension and rarely, polyarthritis. A few anaphylactoid reactions have been reported as well as erythema multiforme, sometimes resembling Stevens-Johnson syndrome. Those reactions may occur in individuals with a history of hypersensitivity to clindamycin or lincomycin.

**INTRAVENOUS LD50 (RAT):** 321 mg/kg (clindamycin phosphate).

**INTRAVENOUS LD50 (MOUSE):** 820 mg/kg (clindamycin phosphate).

**ORAL LD50 (RAT):** 1,832 mg/kg (clindamycin phosphate).

**ORAL LD50 (MOUSE):** 2,359 mg/kg (clindamycin phosphate).

**INTRAPERITONEAL LD50 (RAT):** 745 mg/kg (clindamycin phosphate).

**INTRAPERITONEAL LD50 (MOUSE):** 784 mg/kg (clindamycin phosphate).

**SUBCUTANEOUS LD50 (RAT):** 3,861 mg/kg (clindamycin phosphate).

**SUBCUTANEOUS LD50 (MOUSE):** 1,036 mg/kg (clindamycin phosphate).

**OTHER STUDIES:**

**GENOTOXICITY:** Mutagenicity: clindamycin phosphate was not found to be a mutagen with the Ames assay and did not act as a clastogen or chromosomal mutagen in the micronucleus test.

**TERATOGENICITY:** Although clindamycin phosphate is not teratogenic in the mouse or rat, the safety of the compound in pregnant women has not been established.

**CARCINOGENICITY:** Ingredient(s) are not listed as carcinogenic by IARC, NTP or OSHA.

**12. ECOLOGICAL INFORMATION****ENVIRONMENTAL FATE:**

**MOBILITY:** Clindamycin phosphate melts with decomposition at approximately 175°C. It has no measurable vapor pressure, therefore it is not expected to enter the air. Clindamycin phosphate is freely soluble in water (1 g in 2.5-mL water). Based on its solubility data, clindamycin phosphate is expected to be relatively mobile and migrate toward the aquatic compartment.

**PERSISTENCE/DEGRADABILITY:** No information found.

**BIOACCUMULATIVE POTENTIAL:** The octanol/water partition coefficient of clindamycin phosphate is not known. However, based its water solubility, it would be expected to be less than 3 and thus, would have a low potential to bioaccumulate in aquatic organisms.

**ABIOTIC POTENTIAL:** Clindamycin phosphate may 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 biotic flora of sewage treatment facilities.

**ECOTOXICITY:** No information found.

**13. DISPOSAL CONSIDERATIONS**

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

**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.

**15. OTHER INFORMATION**

**REVIEWED BY:** Health and Safety Regulatory Affairs.

**DISCLAIMER:** The MSDS information is believed to be correct but should only be used as a guide. The Upjohn Company disclaims any express or implied warranty as to the accuracy of the MSDS information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the information.

**16. LABELING**

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

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