

**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- α -D-galacto-
Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-
[[(1-methyl-4-propyl-2-pyrrolidiny)-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/m³

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 is 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, polyarthrititis. 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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