1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Clindamycin Phosphate Vaginal Cream

Trade Name: CLEOCIN; DALACIN
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>2</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>*</td>
</tr>
<tr>
<td>Mineral oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>*</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixed Fatty Acid Esters</td>
<td>Not Assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 60</td>
<td>9005-67-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitan monostearate</td>
<td>1338-41-6</td>
<td>215-664-9</td>
<td>*</td>
</tr>
<tr>
<td>Cetyl/Stearyl alcohol</td>
<td>67762-27-0</td>
<td>267-008-6</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white cream
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed. May cause allergic reaction.

Additional Hazard Information:
Short Term: May cause eye irritation (based on components) May cause mild skin irritation (based on animal data).
Known Clinical Effects: Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused sore throat, fever, gastrointestinal disturbances, abnormal liver function tests, kidney dysfunction. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

EU Indication of danger: Irritant

EU Hazard Symbols:  

EU Risk Phrases: R43 - May cause sensitization by skin contact.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Due to the nature of this material first aid is not normally required. If irritation occurs, wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance.

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.

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

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Clindamycin Phosphate
Pfizer OEL TWA-8 Hr: 0.1mg/m³

Sorbitan monostearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Mineral oil
OSHA - Final PELS - TWAs: = 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA sampled by method that does not collect vapor
ACGIH Threshold Limit Value (STEL) = 10 mg/m³ STEL
ACGIH OELs - Notice of Intended Changes Listed
Australia TWA = 5 mg/m³ TWA

Propylene glycol
Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
Hands: Not required for the normal use of this product. Individuals with known sensitivity should wear protective gloves to avoid skin contact.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities. Individuals with known sensitivity should wear long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this material.
Respiratory protection: Not required for the normal use of this product. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:
Physical State: Cream
Color: White

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Clindamycin Phosphate
- Rat Oral LD50 1832 mg/kg
- Rat Intravenous LD50 321 mg/kg
- Rat Intrapitoneal LD 50 745 mg/kg
- Mouse Oral LD 50 2359 mg/kg
- Mouse Intravenous LD 50 820 mg/kg

Benzyl Alcohol
- Rat Oral LD50 1.23 g/kg
- Rat Intravenous LD50 53 mg/kg

Polysorbate 60
- Rat Oral LD50 64,000 mg/kg

Propylene glycol
- Mouse Oral LD50 22,000 mg/kg
- Rat Oral LD50 20,000 mg/kg
- Rabbit Dermal LD50 20,800 mg/kg

Stearic acid
- Rat Oral LD50 > 4640 mg/kg
- Rabbit Dermal LD50 > 5000 mg/kg

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)

Clindamycin Phosphate
- Eye Irritation Rabbit Moderate
- Skin Irritation Rabbit Mild

Benzyl Alcohol
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Moderate
- Skin Irritation Guinea Pig Moderate
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Stearic acid
Skin Irritation Rabbit Mild

Mineral oil
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

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

Clindamycin Phosphate
6 Month(s) Rat Oral 600 mg/kg/day NOAEL No effects at maximum dose
6 Month(s) Dog Oral 600 mg/kg/day NOAEL Gastrointestinal system

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

Clindamycin Phosphate
Prenatal & Postnatal Development Rat Subcutaneous 250 mg/kg NOAEL Not teratogenic
Prenatal & Postnatal Development Rat Oral 300 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Mouse Oral 600 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rabbit Subcutaneous 5 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity
Reproductive & Fertility Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose

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

Clindamycin Phosphate
Bacterial Mutagenicity (Ames) Salmonella Negative
In Vitro Micronucleus Rat Negative

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

Mineral oil
IARC: Group 3
### 15. REGULATORY INFORMATION

**EU Symbol:** Xi
**EU Indication of danger:** Irritant

**EU Risk Phrases:**
- R43 - May cause sensitization by skin contact.

**EU Safety Phrases:**
- S24 - Avoid contact with skin.
- S36/37 - Wear suitable protective clothing and gloves.

**OSHA Label:**
**WARNING**
May be harmful if swallowed.
May cause allergic reaction.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 2, Subdivision B

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<table>
<thead>
<tr>
<th>Substance</th>
<th>EU EINECS List</th>
<th>Australia (AICS)</th>
<th>United States TSCA - Sect. 8(b)</th>
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<tbody>
<tr>
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<td><strong>Polysorbate 60</strong></td>
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</table>
16. OTHER INFORMATION

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

End of Safety Data Sheet