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

Material Name: Clindamycin Phosphate Sterile Solution

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

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
- Short Term: Active ingredient may be harmful if swallowed. May cause eye irritation; May cause skin irritation. (based on components).
- 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: Xi

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.
2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Xi;R36-43 Xn;R22</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Xn;R20/22</td>
<td>&lt;1.0</td>
<td></td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>139-33-3</td>
<td>205-358-3</td>
<td>Not Listed</td>
<td>&lt;0.1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

For the full text of the R phrases mentioned in this Section, see Section 16

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: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Clindamycin Phosphate

Pfizer OEL TWA-8 Hr: 100µg/m³

Benzyl Alcohol

Bulgaria OEL - TWA: Listed
Czech Republic OEL - TWA: Listed
Latvia OEL - TWA: Listed
Lithuania OEL - TWA: Listed
Poland OEL - TWA: Listed


Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>Clear, colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
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 LD 50 1832 mg/kg
- Rat Intravenous LD 50 321 mg/kg
- Rat Intraperitoneal LD 50 745 mg/kg
- Mouse Oral LD 50 2359 mg/kg
- Mouse Intravenous LD 50 820 mg/kg

**Benzyl Alcohol**
- Rat Oral LD50 1230 mg/kg
- Rat Intravenous LD50 53 mg/kg
- Rat Inhalation LC50 46 mg/m³

**Edetate disodium**
- Rat Oral LD50 2000-2200 mg/kg

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

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
11. TOXICOLOGICAL INFORMATION

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.

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. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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.
15. REGULATORY INFORMATION

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B

Water for Injection
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List
231-791-2

Clindamycin Phosphate
EU EINECS/ELINCS List
246-433-0

Benzyl Alcohol
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List
202-859-9

Edetate disodium
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List
205-358-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R43 - May cause sensitization by skin contact.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources:
Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision:
Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.