SAFETY DATA SHEET

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

Product Identifier
Material Name: Clindamycin Phosphate Vaginal Cream
Trade Name: CLEOCIN; DALACIN; SOBELIN
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet
Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Skin Sensitization: Category 1

Label Elements
Signal Word: Warning
Hazard Statements: H317 - May cause an allergic skin reaction

Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - IF skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Acute Tox.4 (H302)</td>
<td>2</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2A (H319)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit.3 (H316)</td>
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<tr>
<td></td>
<td></td>
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<td>Skin Sens.1 (H317)</td>
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<tr>
<td>Mineral oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
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<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4</td>
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<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
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<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;5</td>
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<td></td>
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<td>Acute Tox.4 (H332)</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Cetyl Palmitate</td>
<td>540-10-3</td>
<td>208-736-6</td>
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<td>Cetyl/Stearyl alcohol</td>
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<td>267-008-6</td>
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<tr>
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<td>Polysorbate 60</td>
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</tr>
<tr>
<td>Sorbitan monostearate</td>
<td>1338-41-6</td>
<td>215-664-9</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.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Clindamycin Phosphate
Pfizer OEL TWA-8 Hr: 100µg/m³

Mineral oil
ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
Belgium OEL - TWA 5 mg/m³
Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 5 mg/m³
Denmark OEL - TWA 1 mg/m³
Finland OEL - TWA 5 mg/m³
Greece OEL - TWA 5 mg/m³
Lithuania OEL - TWA 1 mg/m³
Netherlands OEL - TWA 5 mg/m³
OSHA - Final PELS - TWAs: 5 mg/m³
Poland OEL - TWA 5 mg/m³
Portugal OEL - TWA 5 mg/m³
Romania OEL - TWA 5 mg/m³
Slovakia OEL - TWA 5 ppm
Spain OEL - TWA 1 mg/m³
Sweden OEL - TWAs 5 mg/m³
Vietnam OEL - TWAs 5 mg/m³

Propylene glycol
Australia TWA 150 ppm
10 mg/m³
474 mg/m³
Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³
Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

Benzyl Alcohol
Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 40 mg/m³
Finland OEL - TWA 10 ppm
45 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
Poland OEL - TWA 240 mg/m³

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Cream</th>
<th>Color:</th>
<th>White</th>
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</thead>
<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
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<table>
<thead>
<tr>
<th>Solvent Solubility:</th>
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</thead>
<tbody>
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<td>Water Solubility:</td>
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<tr>
<td>pH:</td>
<td>3-6</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient; (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Clindamycin Phosphate**

- No data available
- Water, purified
- No data available
- Sorbitan monostearate
  - No data available
- Polysorbate 60
  - No data available
- Propylene glycol
  - No data available
- Stearic acid
  - No data available
- Cetyl/Stearyl alcohol
  - No data available
- Mineral oil
  - No data available
- Cetyl Palmitate
  - No data available
- Benzyl Alcohol
  - No data available

**Decomposition Temperature (°C):** No data available.
SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Vaginal Cream

Revision date: 12-Jul-2018

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May be harmful if swallowed. May cause eye 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.

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

Clindamycin Phosphate
- Rat Oral LD 50 1832 mg/kg
- Rat Para-periosteal LD 50 321mg/kg
- Rat Intraperitoneal LD 50 745mg/kg
- Mouse Oral LD 50 2359mg/kg
- Mouse Intravenous LD 50 820mg/kg

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

Propylene glycol
- Rat Oral LD 50 22,000 mg/kg
- Mouse Oral LD 50 24,900mg/kg
- Rabbit Dermal LD 50 20,800mg/kg
11. TOXICOLOGICAL INFORMATION

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

Benzyl Alcohol
Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/L

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

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Stearic acid
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Mild

Mineral oil
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Cetyl Palmitate
Skin Irritation Rabbit Mild

Benzy alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
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

Stearic acid
30 Week(s) Rat Oral 300 ppm LOAEL Adipose tissue
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

Stearic acid
- In Vitro Bacterial Mutagenicity (Ames): *Salmonella* Negative
- Unscheduled DNA Synthesis: *E. coli* Negative

Stearic acid
- 26 Week(s): Rat, Subcutaneous, 0.5 mg/kg/week, NOAEL, Not carcinogenic
- 52 Week(s): Mouse, Subcutaneous, 0.05 mg/kg/week, LOAEL, Tumors

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.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzyl Alcohol
- *Pimephales promelas* (Fathead Minnow): EPA LC50, 96 Hours, 460 mg/L
- *Daphnia magna* (Water Flea): OECD EC50, 48 Hours, 230 mg/L
- *Pseudokirchneriella subcapitata* (Green Alga): OECD EC50, 72 Hours, 500 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol
- *Daphnia magna* (Water Flea): OECD 21 Day(s), EC50, 66 mg/L, Reproduction

Persistence and Degradability: No data available

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Benzyl Alcohol
- OECD Activated sludge: Ready, 92% After 14 Day(s), Ready

Bio-accumulative Potential: No data available

Mobility in Soil: No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Cetyl Palmitate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 208-736-6

Clindamycin Phosphate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: 246-433-0

Cetyl/Stearyl alcohol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 267-008-6

Mineral oil
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Water, purified</td>
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<td>Not Listed</td>
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<td>Present</td>
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<td>200-313-4</td>
</tr>
<tr>
<td>Polysorbate 60</td>
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<tr>
<td>Sorbitan monostearate</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>202-859-9</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Vaginal Cream
Revision date: 12-Jul-2018

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

Revision date: 12-Jul-2018
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet