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

Product Identifier

Material Name: Clindamycin Phosphate Vaginal Cream (Greenstone LLC)
Trade Name: Not applicable
Chemical Family: Not determined

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

2. HAZARDS IDENTIFICATION

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

EU Classification:
EU Indication of danger: Irritant
EU Risk Phrases: R43 - May cause sensitization by skin contact.

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 should 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
SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Vaginal Cream (Greenstone LLC)
Revision date: 21-Aug-2014

Other Hazards
Australian Hazard Classification (NOHSC):

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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Xn; R20/22</td>
<td>Acute Tox. 4 (H302)</td>
<td>&lt;5</td>
</tr>
<tr>
<td></td>
<td>Clindamycin Phosphate</td>
<td>24729-96-2</td>
<td>246-433-0</td>
<td>Xn;R36-43 Xn;R22</td>
<td>Acute Tox.4 (H302) Eye Irrit.2A (H319) Skin Irrit.3 (H316) Skin Sens.1 (H317)</td>
<td>2</td>
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<tr>
<td></td>
<td>Mineral oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cetyl Palmitate</td>
<td>540-10-3</td>
<td>208-736-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cetyl/Stearyl alcohol</td>
<td>67762-27-0</td>
<td>267-008-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Polysorbate 60</td>
<td>9005-67-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sorbitan monostearate</td>
<td>1338-41-6</td>
<td>215-664-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</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 R phrases and 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. 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.
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 fire fighting 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. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid contact with eyes, 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.

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

**Clindamycin Phosphate**
- Manufacturer OEL: 100ug/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: 5 mg/m³
- Sweden OEL - TWAs: 1 mg/m³

**Sorbitan monostearate**
- ACGIH Threshold Limit Value (TWA): 10 mg/m³

### Exposure Controls
**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.

**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>Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<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:</td>
<td>(Method, pH, Endpoint, Value)</td>
</tr>
</tbody>
</table>

Clindamycin Hydrochloride

No data available

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

Benzyl Alcohol

No data available

Cetyl Palmitate

No data available

Decomposition Temperature (°C): No data available.

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

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): 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 various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

Short Term: May cause skin irritation. May be harmful if swallowed. (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 Hydrochloride**
- Rat Oral LD50 2618 mg/kg
- Rat Sub-tenon injection (eye) LD50 279mg/kg
- Rat Subcutaneous LD50 891mg/kg
- Mouse Oral LD50 1479mg/kg
- Mouse Intravenous LD50 143mg/kg

**Clindamycin Phosphate**
- Rat Oral LD50 1832 mg/kg
- Rat Para-periosteal LD50 321mg/kg
- Rat Intraperitoneal LD50 745mg/kg
- Mouse Oral LD50 2359mg/kg
- Mouse Intravenous LD50 820mg/kg

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

**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.
11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Clindamycin Hydrochloride
Eye Irritation  Rat  No effect
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rat  No effect

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

Benzy1 Alcohol
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Moderate
Skin Irritation  Guinea Pig  Moderate

Cetyl Palmitate
Skin Irritation  Rabbit  Mild

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

Clindamycin Hydrochloride
6 Month(s)  Rat  Oral  600 mg/kg/day  NOAEL  No effects at maximum dose
6 Month(s)  Dog  Oral  600 mg/kg/day  LOAEL  Gastrointestinal system
1 Year(s)  Rat  Oral  300 mg/kg/day  NOAEL  No effects at maximum dose
1 Month(s)  Dog  Oral  300 mg/kg/day  NOAEL  No effects at maximum dose

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

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

Clindamycin Hydrochloride
Reproductive & Fertility  Rat  Oral  300 mg/kg/day  NOAEL  Fertility
11. TOXICOLOGICAL INFORMATION

### Embryo / Fetal Development

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Teratogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>250 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>600 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>600 mg/kg/day</td>
<td>NOAEL</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Teratogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clindamycin Phosphate</td>
<td>Rat</td>
<td>Oral</td>
<td>600 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>600 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td></td>
<td>Rabbit</td>
<td>Subcutaneous</td>
<td>250 mg/kg/day</td>
<td>NOAEL</td>
</tr>
</tbody>
</table>

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

- **Clindamycin Hydrochloride**
  - Bacterial Mutagenicity (Ames) *Salmonella* Negative
  - *In Vitro* Micronucleus Negative

- **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

### 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:

No data available

### Persistence and Degradability:

No data available

### 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

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

Benzyl 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 202-859-9

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

Cetyl/Stearyl alcohol
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
15. REGULATORY INFORMATION

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

**Mineral oil**
- 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: 232-384-2

**Polysorbate 60**
- 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: 231-791-2

**Sorbitan monostearate**
- 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: 215-664-9

**Stearic acid**
- 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: 200-313-4

**Water, purified**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
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

Xn - Harmful
Xi - Irritant

R43 - May cause sensitization by skin contact.
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information. Updated Section 11 - Toxicology Information.

Revision date: 21-Aug-2014
Prepared by: Product Stewardship Hazard Communication
Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a 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