

**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**Details of the Supplier of the Safety Data Sheet**Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095**Emergency telephone number:**  
800-435-7095  
CHEMTREC (24 hours): 1-800-424-9300**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

Page 2 of 11

Version: 3.0

**Other Hazards** No data available  
**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn; R20/22	Acute Tox. 4 (H302) Acute Tox. 4 (H332)	<5
Clindamycin Phosphate	24729-96-2	246-433-0	Xi;R36-43 Xn;R22	Acute Tox.4 (H302) Eye Irrit.2A (H319) Skin Irrit.3 (H316) Skin Sens.1 (H317)	2
Mineral oil	8012-95-1	232-384-2	Not Listed	Not Listed	*
Stearic acid	57-11-4	200-313-4	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Cetyl Palmitate	540-10-3	208-736-6	Not Listed	Not Listed	*
Cetyl/Stearyl alcohol	67762-27-0	267-008-6	Not Listed	Not Listed	*
Polysorbate 60	9005-67-8	Not Listed	Not Listed	Not Listed	*
Sorbitan monostearate	1338-41-6	215-664-9	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*

**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.

## SAFETY DATA SHEET

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

Page 3 of 11

Version: 3.0

**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 CO<sub>2</sub>, 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

## SAFETY DATA SHEET

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

Page 4 of 11

Version: 3.0

### 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/m <sup>3</sup>
Czech Republic OEL - TWA	40 mg/m <sup>3</sup>
Finland OEL - TWA	10 ppm
	45 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Poland OEL - TWA	240 mg/m <sup>3</sup>

#### Clindamycin Phosphate

Manufacturer OEL:	100ug/m <sup>3</sup>
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#### Mineral oil

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
Belgium OEL - TWA	5 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	5 mg/m <sup>3</sup>
Denmark OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Greece OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	5 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 mg/m <sup>3</sup>
Romania OEL - TWA	5 mg/m <sup>3</sup>
Slovakia OEL - TWA	5 ppm
	1 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Spain OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>

#### Sorbitan monostearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
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#### 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.

## SAFETY DATA SHEET

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

**Page 5 of 11**

**Version: 3.0**

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**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

<b>Physical State:</b>	Cream	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	3-6
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**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

## SAFETY DATA SHEET

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

Page 6 of 11

Version: 3.0

### 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 LD 50 2618 mg/kg  
Rat Sub-tenon injection (eye) LD 50 279mg/kg  
Rat Subcutaneous LD 50 891mg/kg  
Mouse Oral LD 50 1479mg/kg  
Mouse Intravenous LD 50 143mg/kg

##### 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

##### 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.

## SAFETY DATA SHEET

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

Page 7 of 11

Version: 3.0

### 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

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

##### **Clindamycin Hydrochloride**

Reproductive & Fertility	Rat	Oral	300 mg/kg/day	NOAEL	Fertility
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## SAFETY DATA SHEET

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

Page 8 of 11

Version: 3.0

### 11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development	Mouse	Oral	600 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	600 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	250 mg/kg/day	NOAEL	Not Teratogenic

#### 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 Hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Micronucleus		Negative

##### Clindamycin Phosphate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Micronucleus	Rat	Negative

##### Stearic acid

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Unscheduled DNA Synthesis	<i>E. coli</i>	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

<b>Environmental Overview:</b>	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available



## SAFETY DATA SHEET

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

Page 9 of 11

Version: 3.0

### 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

## SAFETY DATA SHEET

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

Page 10 of 11

Version: 3.0

### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	267-008-6
<b>Clindamycin Phosphate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	246-433-0
<b>Mineral oil</b>	
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
<b>Polysorbate 60</b>	
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	Not Listed
<b>Sorbitan monostearate</b>	
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
<b>Stearic acid</b>	
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
<b>Water, purified</b>	
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

## SAFETY DATA SHEET

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

**Page 11 of 11**

**Version: 3.0**

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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  
Product Stewardship Hazard Communication  
**Prepared by:** 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**