



# SAFETY DATA SHEET

Revision date: 02-Feb-2015

Version: 2.0

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

### Product Identifier

**Material Name:** Trandolapril/Verapamil Tablets

**Trade Name:** Not applicable

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product for the treatment of high blood pressure (hypertension) angina

### Details of the Supplier of the Safety Data Sheet

Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095

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

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 3  
Reproductive Toxicity: Category 2  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2

#### EU Classification:

EU Indication of danger: Toxic  
Toxic to Reproduction: Category 3  
Dangerous for the Environment

#### EU Risk Phrases:

R25 - Toxic if swallowed.  
R63 - Possible risk of harm to the unborn child.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:**  
H301 - Toxic if swallowed  
H361d - Suspected of damaging the unborn child  
H401 - Toxic to aquatic life  
H411 - Toxic to aquatic life with long lasting effects

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**Precautionary Statements:**

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P273 - Avoid release to the environment
- P281 - Use personal protective equipment as required
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P391 - Collect spillage
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations



**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
 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	%
Sodium alginate	9005-38-3	Not Listed	Not Listed	Not Listed	*
Verapamil Hydrochloride	152-11-4	205-800-5	T; R25Cat.3, R63;R51/53	Acute Tox. 3, H301 Repr. 2, H361dAcute 2,H401Chronic 2,H411	30
Titanium dioxide	13463-67-7	236-675-5	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Trandolapril	87679-37-6	Not Listed	Repr.Cat.3;R63	Not Listed	1.0
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	Not Listed	*

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**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. 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:** May emit toxic fumes such as oxides of nitrogen and chlorine gas.

**Fire / Explosion Hazards:** Not applicable

#### 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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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**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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>

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Slovakia OEL - TWA 4 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>

### Manufacturer OEB Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Trandolapril

#### Manufacturer OEB:

OEB4 (control exposure to the range of >1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

#### Verapamil Hydrochloride

#### Manufacturer OEB:

OEB3 (control exposure to the range of >10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

### 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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablets	<b>Color:</b>	Pink, White, Gold, or Reddish brown
<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>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

**Sodium alginate**  
No data available

**Microcrystalline cellulose**  
No data available

**Lactose NF, monohydrate**  
No data available

**Povidone**  
No data available

**Starch**  
No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Hydroxypropyl methylcellulose

No data available

#### Titanium dioxide

No data available

#### Trandolapril

No data available

#### Verapamil Hydrochloride

Measured Log P 3.79

**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 under normal conditions of use.

#### 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.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, kidneys, ureter, bladder (based on components) .

**Known Clinical Effects:** May cause slow heart rate (bradycardia), decrease in blood pressure (hypotension), dizziness. Occasional, transient changes reported in liver function tests, but no liver damage seen. This material has been shown to be secreted in low concentrations in human breast milk.

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

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

##### Povidone

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### 11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 100 g/kg

#### Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

#### Trandolapril

Rat Oral LD50 > 5000 mg/kg

Rat Para-periosteal LD50 > 2000mg/kg

#### Verapamil Hydrochloride

Rat Oral LD 50 108 mg/kg

Mouse Oral LD 50 163mg/kg

Rat Intravenous LD 50 16mg/kg

Mouse Intravenous LD 50 5795mg/kg

Rat Subcutaneous LD 50 107mg/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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

##### Verapamil Hydrochloride

Skin Irritation Rabbit Mild

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

##### Trandolapril

Embryo / Fetal Development Rat Oral 300 mg/kg/day NOAEL Not teratogenic

Fertility and Embryonic Development Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose

##### Verapamil Hydrochloride

Reproductive & Fertility Rat Oral 55 mg/kg/day NOAEL Fertility

Embryo / Fetal Development Rat Oral 60 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rat Oral 60 mg/kg/day LOAEL Fetotoxicity

Embryo / Fetal Development Rabbit Oral 15 mg/kg/day NOAEL Not Teratogenic

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

##### Trandolapril

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

*In Vivo* Micronucleus Mouse Negative

##### Verapamil Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative



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### 11. TOXICOLOGICAL INFORMATION

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Trandolapril

78 Week(s) Mouse Oral 25 mg/kg/day NOAEL Not carcinogenic  
104 Week(s) Rat Oral 8 mg/kg/day NOAEL Not carcinogenic

##### Verapamil Hydrochloride

18 Month(s) Rat Oral 58 mg/kg/day NOAEL Not carcinogenic  
2 Year(s) Rat Oral 120 mg/kg/day NOAEL Not carcinogenic

**Carcinogen Status:** See below

##### Povidone

**IARC:** Group 3 (Not Classifiable)

##### Titanium dioxide

**IARC:** Group 2B (Possibly Carcinogenic to Humans)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Toxic to aquatic life with long lasting effects.

#### **Toxicity:**

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

##### Verapamil Hydrochloride

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 2.72 mg/L  
*Daphnia magna* (Water Flea) LC50 48 Hours 7.04 mg/L

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

##### Verapamil Hydrochloride

*Pimephales promelas* (Fathead Minnow) OECD 28 Day(s) NOEC 0.3 mg/L Growth  
*Pimephales promelas* (Fathead Minnow) OECD 28 Day(s) NOEC 0.6 mg/L Survival

#### **Persistence and Degradability:**

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

**Bio-accumulative Potential:** No data available

##### Verapamil Hydrochloride

Measured Log P 3.79

**Mobility in Soil:** No data available

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### 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 1, Subdivision B

Class D, Division 2, Subdivision A



#### Sodium alginate

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

#### Trandolapril

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

#### Verapamil Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present

**SAFETY DATA SHEET**

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**15. REGULATORY INFORMATION**

EU EINECS/ELINCS List	205-800-5
<b>Titanium dioxide</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5
<b>Lactose NF, monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed
<b>Povidone</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>Microcrystalline cellulose</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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9
<b>Starch</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	232-679-6
<b>Hydroxypropyl methylcellulose</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

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### 16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed  
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child  
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Toxic to Reproduction: Category 3  
T - Toxic  
N - Dangerous for the environment

R25 - Toxic if swallowed.  
R63 - Possible risk of harm to the unborn child.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**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 9 - Physical and Chemical Properties. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

**Revision date:** 02-Feb-2015  
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**