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

Revision date: 02-Feb-2015
Version: 2.0

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
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):


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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium alginate</td>
<td>9005-38-3</td>
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<td>Not Listed</td>
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<tr>
<td>Verapamil Hydrochloride</td>
<td>152-11-4</td>
<td>205-800-5</td>
<td>T; R25Cat.3, R63; R51/53</td>
<td>Acute Tox. 3, H301 Repr. 2, H361dAcute 2,H401Chronic 2,H411</td>
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<td>Titanium dioxide</td>
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<td>236-675-5</td>
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<tr>
<td>Microcrystalline cellulose</td>
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<td>232-674-9</td>
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<td>*</td>
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<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
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<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>Trandolapril</td>
<td>87679-37-6</td>
<td>Not Listed</td>
<td>Repr.Cat.3;R63</td>
<td>Not Listed</td>
<td>1.0</td>
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<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
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<td>Not Listed</td>
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<td>*</td>
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<tr>
<td>Povidone</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Trandolapril/Verapamil Tablets
Revision date: 02-Feb-2015
Version: 2.0

Additiona 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.
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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Titanium dioxide

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>ACGIH OELs - Notice of Intended Changes</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
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<tr>
<td>Belgium OEL - TWA</td>
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<td>Greece OEL - TWA</td>
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<tr>
<td>Ireland OEL - TWAs</td>
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<td>Poland OEL - TWA</td>
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<td>Portugal OEL - TWA</td>
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<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
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<td>Sweden OEL - TWAs</td>
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Microcrystalline cellulose

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Starch

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SAFETY DATA SHEET

Material Name: Trandolapril/Verapamil Tablets
Revision date: 02-Feb-2015
Page 6 of 12
Version: 2.0

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.

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:
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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
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<tbody>
<tr>
<td>Odor:</td>
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<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
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<tr>
<td>Solvent Solubility:</td>
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<tr>
<td>Water Solubility:</td>
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<tr>
<td>pH:</td>
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<tr>
<td>Melting/Freezing Point (°C):</td>
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<tr>
<td>Boiling Point (°C):</td>
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<tr>
<td>Odor Threshold:</td>
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<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
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</table>

Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³

Slovakia OEL - TWA
Spain OEL - TWA

Manufacturer OEB:
Trandolapril
Manufacturer OEB: OEB4 (control exposure to the range of >1ug/m³ to <10ug/m³)
Verapamil Hydrochloride
Manufacturer OEB: OEB3 (control exposure to the range of >10ug/m³ to < 100ug/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.
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<td>pH:</td>
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Spain OEL - TWA 10 mg/m³

Slovakia OEL - TWA
Spain OEL - TWA

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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

Hydroxypropyl methylcellulose
No data available.

Titanium dioxide
No data available.

Trandolapril
No data available.

Verapamil Hydrochloride
Measured \( \text{Log P} \) 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: 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
11. TOXICOLOGICAL INFORMATION

### 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
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
Onchorhynchus 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 Day(s) NOEC 0.3 mg/L Growth
Pimephales promelas (Fathead Minnow) OECD 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

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 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

PZ02181
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>California Proposition 65</th>
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<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
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<th>California Proposition 65</th>
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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
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