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

Material Name: Finasteride Tablets (Greenstone LLC)

| Trade Name: | Not applicable |
| Synonyms: | None |
| Chemical Family: | 5-alpha reductase inhibitor |
| Intended Use: | Pharmaceutical product for the treatment of, benign prostatic hyperplasia, male pattern baldness |

2. HAZARDS IDENTIFICATION

Appearance: Blue tablets
Signal Word: WARNING

Statement of Hazard:
Harmful if swallowed.
Suspected of damaging the unborn child.

Additional Hazard Information:
- **Short Term:** May be absorbed through the skin and cause systemic effects.
- **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus.

Known Clinical Effects:
Clinical use of this drug has caused hypersensitivity reactions, skin rash, hives, redness and swelling of the skin (urticaria) impotence, sexual disturbances, and changes in sexual desire (libido).

EU Indication of danger:
- Harmful
- Toxic to Reproduction: Category 3

EU Risk Phrases:
- R22 - Harmful if swallowed.
- R63 - Possible risk of harm to the unborn child.

Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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<td>*</td>
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<tr>
<td>Ferric oxide yellow</td>
<td>51274-00-1</td>
<td>257-098-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Finasteride</td>
<td>98319-26-7</td>
<td>Not Listed</td>
<td>Repr.Cat.3;R63 Xn;R22</td>
<td>5 mg***</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<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>*</td>
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<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Blue No. 2 Lake</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Docusate Sodium</td>
<td>577-11-7</td>
<td>209-406-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

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

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.

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

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

General Handling: Restrict access to work area. 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 hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store as directed by product packaging.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Talc (non-asbestiform)**

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 fiber/cm³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.3 fiber/cm³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>0.8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>

**Titanium dioxide**

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
</tbody>
</table>
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, disposable gloves (double suggested) 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 disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

MATERIAL SAFETY DATA SHEET

Material Name: Finasteride Tablets (Greenstone LLC)
Revision date: 13-Apr-2012

Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Finasteride
Manufacturer OEB: OEB5 (control exposure to <1ug/m³)

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, disposable gloves (double suggested) 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 disposable 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>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>Blue</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**Partition Coefficient**

- **Partition Coefficient (Calculated - Log Pow/Log Kow):** 3.24 (Finasteride)
- **Partition Coefficient (Calculated; pH 7.4 - Log D):** 3.24 (Finasteride)

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.
**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

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

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

- **Lactose Monohydrate**
  - Rat Oral LD50 29700 mg/kg

- **Microcrystalline cellulose**
  - Rat Oral LD50 > 5000 mg/kg
  - Rabbit Dermal LD50 > 2000 mg/kg

- **Magnesium stearate**
  - Rat Oral LD50 > 2000 mg/kg
  - Rat Inhalation LC50 > 2000 mg/m³

- **Hydroxypropyl methylcellulose**
  - Rat Oral LD50 > 10,000 mg/kg

- **Titanium dioxide**
  - Rat Oral LD50 > 7500 mg/kg
  - Rat Subcutaneous LD50 50 mg/kg

- **Finasteride**
  - Rat Oral LD50 418 mg/kg
  - Mouse Oral LD50 486 mg/kg

- **Talc (non-asbestiform)**
  - Rat Oral LD50 > 1600 mg/kg
11. TOXICOLOGICAL INFORMATION

Microcrystalline cellulose
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Finasteride
Prenatal & Postnatal Development  Rat  No route specified  \( \geq 30 \) ug/kg/day  LOAEL  Developmental toxicity
Embryo / Fetal Development  Monkey  Intravenous  800 ng/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Monkey  Oral  2 mg/kg/day  LOAEL  Developmental toxicity
Reproductive & Fertility-Males  Rat  No route specified  80 mg/kg/day  NOAEL  No effects at maximum dose

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

Lactose Monohydrate
In Vitro Bacterial Mutagenicity (Ames)  Negative

Finasteride
In Vitro Bacterial Mutagenicity (Ames)  Not specified  Negative
In Vitro Mammalian Cell Mutagenicity  Not specified  Negative
In Vitro Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive
In Vivo Chromosome Aberration  Mouse  Negative

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

Finasteride
24 Month(s)  Rat  No route specified  160(male), 320(female) mg/kg/day  NOAEL  Not carcinogenic
19 Month(s)  Mouse  No route specified  2.50 mg/kg/day  NOAEL  Not carcinogenic
1 Year(s)  Dog  No route specified  45 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)
OSHA:  Listed

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Partition Coefficient
(Calculated - Log Pow/Log Kow):  3.24 (Finasteride)
Partition Coefficient
(Calculated; pH 7.4 - Log D):  3.24 (Finasteride)
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

EU Indication of danger: Harmful
Toxic to Reproduction: Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

Sodium starch glycolate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
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<td>Present</td>
<td>232-674-9</td>
</tr>
<tr>
<td>Australia (AICS):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
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<td>236-675-5</td>
</tr>
<tr>
<td>Australia (AICS):</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
<td>Present</td>
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<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Present</td>
<td>Present</td>
<td>232-679-6</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>Present</td>
<td>Present</td>
<td>232-674-9</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ferric oxide yellow</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Docusate Sodium</td>
<td>Present</td>
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</tr>
<tr>
<td>Finasteride</td>
<td>Schedule 4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.
Reasons for Revision: Updated Section 2 - Hazard Identification.
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