

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

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

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

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

Xn

**EU Risk Phrases:**

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	*
Finasteride	98319-26-7	Not Listed	Repr.Cat.3;R63 Xn;R22	5 mg***

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Lactose Monohydrate	64044-51-5	Not Listed	Not Listed	*
FD&C Blue No. 2 Lake	Not assigned	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Docusate Sodium	577-11-7	209-406-4	Not Listed	*

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.

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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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³ 6.0 mg/m ³ 3.0 mg/m ³
Czech Republic OEL - TWA	2.0 mg/m ³ 10 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³ 5 mg/m ³
Greece OEL - TWA	10 mg/m ³ 2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	10 mg/m ³ 0.8 mg/m ³
Lithuania OEL - TWA	2 mg/m ³ 1 mg/m ³
Netherlands OEL - TWA	0.25 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m ³ 1.0 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Slovakia OEL - TWA	2 mg/m ³ 10 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³ 1 mg/m ³

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³ 5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³ 4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³

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Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Starch, pregelatinized	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Microcrystalline cellulose	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Magnesium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Finasteride	
Manufacturer OEB:	OEB5 (control exposure to <1ug/m ³)
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, 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.

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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

Physical State:	Tablet	Color:	Blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture
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

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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 ≥ 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)

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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

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

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15. REGULATORY INFORMATION

Hydroxypropyl methylcellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

Starch, pregelatinized

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

Lactose Monohydrate

Australia (AICS):	Present
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Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Ferric oxide yellow

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	257-098-5

Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Docusate Sodium

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-406-4

Finasteride

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
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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