SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: Finasteride Tablets (1 mg)

SDS No: P00000020013

Synonyms, Trade Names:
PROPECIA, PROPESHIA, PROHAIR, MK-0906 Tablets (1mg)

Manufacturer:
Merck
One Merck Drive P.O. Box 100
Whitehouse Station, NJ, USA 08889-0100

Telephone: 908-423-1000 (General Information Only)
Fax: 908-735-1496

Contact Person: EHS Data Steward
e-mail: MSDS@merck.com

Emergency telephone: 1-908-423-6000 (24/7/365) English Only

Intended Use: Finished pharmaceutical product: Indicated for the treatment of male pattern hair loss. Intended for men only.

2 HAZARDS IDENTIFICATION

Emergency Overview:

Appearance:	
Color:	Tan
Form :	Tablets
Odor:	Odorless
Signal words	DANGER!
Potential Health Effects:	
General	Finished pharmaceutical product. AVOID EXPOSURE TO CRUSHED OR BROKEN TABLETS IF YOU ARE OR MIGHT BE PREGNANT. May damage fertility. May damage the unborn child. No specific hazard with intact tablets or capsules. In case of exposure to crushed or broken tablets/capsules, avoid contact with eyes and avoid prolonged or repeated contact with skin. Wash thorougly after handling. May cause long-term adverse effects in the aquatic environment. Do not allow runoff to sewer, waterway or ground.
Potential Physical / Chemical Effects:	None expected with normal handling of finished product. Avoid conditions which create dust.
Inhalation:	No specific hazard with intact tablets or capsules. Avoid breathing dust.
skin:	No specific hazard with intact tablets or capsules. Avoid contact with skin.
eye:	No specific hazard with intact tablets or capsules.
Ingestion:	Intended route for clinical use.

Routes of Exposure:	Inhalation
Target Organs:	prostate gland
OSHA Regulatory Status	This product is hazardous according to OSHA 29CFR 1910.1200.
Environment:	May cause long-term adverse effects in the aquatic environment.
OTHER INFORMATION	AVOID EXPOSURE TO CRUSHED OR BROKEN TABLETS IF YOU ARE OR MIGHT BE PREGNANT.

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

Hazardous Component(s):

Chemical name	CAS-No.	Concentration
Cellulose Microcrystalline	9004-34-6	10%
Starch	9005-25-8	10%
FINASTERIDE	98319-26-7	0.65%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation:	Move to fresh air. For breathing difficulties, oxygen may be necessary. If breathing stops, provide artificial respiration. Get medical attention.
Skin contact:	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing.
Eye contact:	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms occur.
Ingestion:	Do not induce vomiting. Get medical attention if symptoms occur.
Notes to the physician:	
Hazards:	See Sections 2 and 11.
Treatment:	Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media:	Water spray, fog, CO2, dry chemical, or alcohol resistant foam.
Unsuitable extinguishing media:	None known.
Unusual Fire & Explosion Hazards:	Emits toxic fumes under fire conditions.
Special Fire Fighting Procedures:	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Keep unnecessary personnel away.

Environmental precautions: Do not release into the environment.

Spill Cleanup Methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Avoid dusty conditions and prevent wind dispersal. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

Handling: No specific hazard with intact tablets or capsules. In case of exposure to crushed or broken tablets/capsules, avoid contact with eyes and avoid prolonged or repeated contact with skin. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

Chemical name	Type	Exposure Limit values	Source
Cellulose Microcrystalline	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (2009)
Cellulose Microcrystalline - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Cellulose Microcrystalline - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Starch	TWA	10 mg/m3	US. ACGIH Threshold Limit Values (2009)
Starch - Respirable fraction.	PEL	5 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Starch - Total dust.	PEL	15 mg/m3	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
FINASTERIDE	TWA	0.5 ug/m3 (OEB 5)	Merck
	Wipe Limit	5 ug/100 cm2	Merck

OEB (Occupational Exposure Band) is an internal Merck control band.

Protective Measures: No special containment required with normal handling of finished product. Use local exhaust ventilation to control residual dust from broken or crushed tablets when handling in bulk quantities.

Respiratory Protection: No specific recommendation made, but respiratory protection must be used if the general level exceeds the Recommended Occupational Exposure Limit

Hand protection: Disposable chemical resistant gloves wherever the potential exists for direct exposure to residual dust from crushed or broken tablets or capsules.

Eye protection:	If contact is likely, safety glasses with side shields are recommended.
Skin and Body Protection:	Work uniform or laboratory coat when there is potential for direct contact with the residual dust from crushed or broken tablets.
Hygiene measures:	Wash skin thoroughly with soap and water.

9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:	
Physical State:	Solid
Form:	Tablets
Color:	Tan
Odor:	Odorless
Flammability (solid, gas):	This product is not flammable.
Partition coefficient (n-octanol/water):	3.5 Active Pharmaceutical Ingredient. Log Kow at pH 7
Other information:	
VOC Content:	0 g/l

10 STABILITY AND REACTIVITY

Stability:	Stable
Possibility of hazardous reactions:	Stable
Conditions to avoid:	Moisture. Excessive heat.
Incompatible materials:	None under normal conditions.
Hazardous decomposition products:	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11 TOXICOLOGICAL INFORMATION

General information:	The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Specified substance(s):

Acute Toxicity (Oral);

Name	Test results
Cellulose Microcrystalline	LD50 (Rat): > 5,000 mg/kg
Starch	No data available.
FINASTERIDE	LD50 (Rat, Female): 373 mg/kg (F) LD50 (Rat, Male): 828 mg/kg (M) LD50 (Mouse, Female): 486 mg/kg (F)

Acute Toxicity (Dermal):

Name	Test results
Cellulose Microcrystalline	LD50 (Rabbit): > 2,000 mg/kg
Starch	No data available.
FINASTERIDE	No data available.

Acute Toxicity (Inhalation):

Name	Test results
Cellulose Microcrystalline	LC50 (Rat, 4 h): > 5.05 mg/l
Starch	No data available.
FINASTERIDE	No data available.

Repeated dose toxicity:

Name	Test results
Cellulose Microcrystalline	No data available.
Starch	No data available.
FINASTERIDE	NOAEL (Rat, Oral, 365 d, daily): 20 mg/kg LOAEL (Rat, Oral, 365 d, daily): >= 40 mg/kg Increase incidence of testicular Leydig cell hyperplasia. NOAEL (Dog, Oral, 365 d, daily): 45 mg/kg Increase incidence of testicular Leydig cell hyperplasia.

Inhalation: No specific hazard with intact tablets or capsules. Avoid breathing dust.

Ingestion: Intended route for clinical use.

Skin corrosion/irritation: No specific hazard with intact tablets or capsules. Avoid contact with skin.

Serious eye damage/eye irritation: No specific hazard with intact tablets or capsules.

Respiratory sensitizer/Skin sensitizer: No data available for finished product.

Carcinogenicity: Active pharmaceutical ingredient: Non-carcinogenic in mice and rats. Benign testicular tumors were observed in mice. Not listed as carcinogen by OSHA, NTP or IARC.

Mutagenesis: No data available for finished product. Active pharmaceutical ingredient: Negative in a battery of in vitro and in vivo genotoxicity assays.

Reproductive toxicity: Active pharmaceutical ingredient: Adverse developmental and reproduction effects were observed in rats. Women who are or might be pregnant should take appropriate steps to minimize exposure.

Other Effects: AVOID EXPOSURE TO CRUSHED OR BROKEN TABLETS IF YOU ARE OR MIGHT BE PREGNANT. In clinical use adverse reactions include: breast tenderness and enlargement, lip swelling, skin rash, impotence, decreased libido and volume of ejaculate.

12 ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: Active pharmaceutical ingredient: Mixture Multiplying Factor (M): 1

Specified substance(s):

Acute toxicity(Fish):

Name	Test results
Cellulose Microcrystalline	LC50 (Trout family (Salmonidae), 96 h): > 100% Saturated solution.
Starch	No data available.
FINASTERIDE	LC50 (Rainbow Trout (Oncorhynchus mykiss), 96 h): 19.6 mg/l

Chronic Toxicity(Fish):

Name	Test results
Cellulose Microcrystalline	No data available.
Starch	No data available.
FINASTERIDE	No data available.

Acute toxicity(Aquatic invertebrates):

Name	Test results
Cellulose Microcrystalline	LC50 (Water Flea, 48 h): > 100 % Saturated solution.
Starch	No data available.
FINASTERIDE	LC50 (Water flea (Daphnia magna), 48 h): 21 mg/l NOEC (Water flea (Daphnia magna), 48 h): 5.3 mg/l

Chronic Toxicity(Aquatic invertebrates):

Name	Test results
Cellulose Microcrystalline	No data available.
Starch	No data available.
FINASTERIDE	LOEC (Water flea (Daphnia magna), 21 d): 0.3 mg/l NOEC (Water flea (Daphnia magna), 21 d): 0.12 mg/l

Acute toxicity(Aquatic plants):

Name	Test results
Cellulose Microcrystalline	EC 50 (Algae, algal mat (Algae), 96 h): > 100% Saturated solution.
Starch	No data available.
FINASTERIDE	NOEC (Green algae (Selenastrum capricornutum), 14 d): 49 mg/l

Persistence and degradability: No data available for finished product. Active pharmaceutical ingredient: Not readily biodegradable

Bioaccumulative potential: No data available for finished product. Active pharmaceutical ingredient: Not likely to bioaccumulate based on log Kow

Mobility: No data available for finished product.

13 DISPOSAL CONSIDERATIONS

Disposal Methods: Do not allow runoff to sewer, waterway or ground. Discharge, treatment, or

disposal may be subject to national, state, or local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14 TRANSPORT INFORMATION

DOT
Not regulated.

IMDG - International Maritime Dangerous Goods Code
Not regulated.

IATA - International Air Transport Association
Not regulated.

15 REGULATORY INFORMATION

US Regulations

- **CERCLA Hazardous Substance List (40 CFR 302.4):**
  None

- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**
  None

- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**
  None

SARA Title III

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**
  None

- **Section 313 Toxic Release Inventory (40 CFR 372):**
  None present or none present in regulated quantities.

State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**
  No ingredient regulated by CA Prop 65 present.

- **Massachusetts Right-To-Know List:**

Cellulose Microcrystalline	Listed
Starch	Listed
Talc	Listed
Titanium Dioxide	Listed

- **New Jersey Right-To-Know List:**

Talc	Listed
Titanium Dioxide	Listed

- **Pennsylvania Right-To-Know List:**

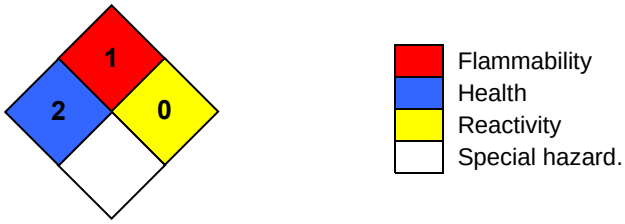
Cellulose Microcrystalline	Listed
Starch	Listed

16 OTHER INFORMATION

OTHER INFORMATION

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

NFPA Hazard ID



Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

Revision Information: Relevant changes have been made in the following sections:
SECTION 1: Identification of the substance/mixture and of the company/undertaking
SECTION 2: Hazards identification
SECTION 3: Composition/information on ingredients
SECTION 4: First aid measures
SECTION 8: Exposure controls/personal protection
SECTION 9: Physical and chemical properties
SECTION 11: Toxicological information
SECTION 12: Ecological information

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Disclaimer: This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.