# SAFETY DATA SHEET

**PRODUCT NAME:** **PROSCAR Tablets** **Page: 1/6**
**PLANT MSDS CODE:** **MHHD-222** **Validated on 21-Dec-2005**

## 1. Product and Company Identification

Manufactured/Supplied by

U.S. HUMAN HEALTH
A Division of Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486

Emergency Telephone Number
1-800-NSC-MERCK (1-800-672-6372)
Merck National Service Center (MNSC)

Label Name: PROSCAR Tablets

Chemical Name: **FINASTERIDE:**
4-azaandrost-1-ene-17-carboxamide,
N-(1,1-Dimethylethyl)-3-oxo-,(5alpha,
17beta)-

Synonyms: Finasteride

Material Product Number: 3094 (5 mg)

Intended Use: Treatment of symptomatic benign prostatic hyperplasia in men with enlarged prostate.

## 2. Composition/Information on Ingredients

| Component | Molecular Formula | Molecular weight | CAS Number | Percent (%) |
|---|---|---|---|---|
| FINASTERIDE | C23H36N2O2 | 372.55 | 98319-26-7 | 4 |
| Inactive ingredients | - - - | Not available. | - - - | 96 |

*While this product is exempt from the requirements of the OSHA Hazard Communication Standard, this MSDS contains valuable information critical to the safe handling of the product in the workplace. This MSDS should be made available to employees who handle the product.*

EC Label

This product is not classified according to the EU regulations.

## 3. Hazards Identification

Appearance: Blue, modified apple-shaped, film-coated tablets.

Emergency Overview: CAUTION!

FINISHED PHARMACEUTICAL PRODUCT.
Type II 5alpha-REDUCTASE INHIBITOR.
MAY CAUSE BIRTH DEFECTS.

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**AVOID EXPOSURE TO CRUSHED OR BROKEN TABLETS IF YOU ARE OR MIGHT BE PREGNANT.**

No specific hazard with intact tablets. In case of exposure to crushed or broken tablets avoid contact with skin and eyes and wash thoroughly after handling. Avoid exposure to crushed tablets during pregnancy. Avoid dusting when handling and avoid all possible sources of ignition (spark or flame). Avoid contact with spilled materials and runoff with soil and surface waterways.

Potential Health Effects — See Section 11 for detailed information.

## 4. First Aid Measures

Eye Contact — No emergency procedures necessary for intact tablets. If exposure occurs to crushed or broken tablets, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact — No emergency procedures necessary for intact tablets. If exposure occurs to crushed tablets, wash with soap and water. Get medical attention if irritation develops. For women who are or might be pretnant, a doctor should be consulted (See Notes to Physician).

Inhalation — No emergency procedures necessary for intact tablets. If overexposure to dust from crushed tablets occurs, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms appear.

Ingestion — Practically non-toxic if swallowed. Physician decision to treat is dependent on amount ingested. For women who are or might be pretnant, a doctor should be consulted (See Notes to Physician).

Notes to physician — Because of the ability of Type II 5 alpha-reductase inhibitors to inhibit the conversion of testosterone to dihydrotestosterone, finasteride may cause abnormalities of external genitalia of a male fetus of a pregnant woman who receives finasteride.

For additional guidance refer to the current prescribing information or the local poison control center.

## 5. Fire Fighting Measures

Flash Point — Not applicable.

Flammable Limits (% in air) — Not applicable.

Autoignition Temperature — Not relevant under normal conditions of product handling.

Oxidizing Properties — Not available.

Combustibility Information — Not relevant under normal conditions of product handling.

Dust Explosivity Information — Not relevant under normal conditions of product handling.If large quantities of dust related to the tablets are encountered, dust explosivity could be an issue.

Shock Sensitivity — No.

Fire/Explosion Hazards — None known under normal conditions of product handling.

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| | |
|---|---|
| Special Fire Procedures | Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear. |
| Extinguishing Media | Use foam or all purpose dry chemicals to extinguish. This material is harmful to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain. |
| Hazardous Decomposition Products | These products are carbon oxides, nitrogen oxides. |

## 6. Accidental Release Measures

| | |
|---|---|
| Personal Precautions | Not necessary for small spills. For large spills, immediately contact emergency personnel. Keep unnecessary personnel away. Women who are or might be pregnant should not be exposed to crushed or broken tablets. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5). |
| Methods for cleaning up | For a small spill, tablets should be collected and disposed of as pharmaceutical waste.<br>For large spills, if emergency personnel are unavailable vacuum or carefully scoop up spilled materials and place in an appropriate container for disposal. Avoid creating dusty conditions and prevent wind dispersal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. **See Section 13 for Waste Disposal Information.** |

For additional assistance in the U.S., CHEMTREC provides a toll-free Hotline for chemical emergencies regarding spills, leaks, exposure or accidents: 1-800-424-9300.
For emergency calls from outside the U.S.: 1-703-527-3887

## 7. Handling and Storage

| | |
|---|---|
| Handling | No specific hazard with intact tablets. In case of exposure to crushed or broken capsules avoid contact with skin and eyes and wash thoroughly after handling. Women who are or might be pregnant should not be exposed to crushed or broken tablets. Avoid dusting when handling and avoid all possible sources of ignition (spark or flame). Avoid contact of spilled material and runoff with soil and surface waterways. |
| Storage | Keep container in a cool, well-ventilated area. Keep container tightly closed and sealed until ready for use.Store tablets at room temperatures below 15-30°C (59-86°F). |

## 8. Exposure Controls/Personal Protection

Exposure Guidelines

| Component | OSHA Permissible Exposure Limit (PEL) | ACGIH Threshold Limit Value (TLV) | Merck Exposure Control Limit (ECL) |
|---|---|---|---|
| FINASTERIDE | Not established | Not established | 0.0005 mg/m$^3$(TWA)* |
| Inactive ingredients | Not established | Not established | Not established |

*For external surfaces use wipe test criteria value of 0.005 mg/100cm$^2$.

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**Engineering Controls**

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|---|---|
| Ventilation | None required with normal handling of finished product. |
| Personal Protective Equipment | |
| Eye/Face Protection | None required with normal handling of finished product. Impervious gloves recommended if the potential exists for direct exposure to broken or crushed tablets. |
| Hand/Arm Protection | No specific hazard with intact tablets. In case of exposure to crushed or broken tablets avoid contact with skin and eyes and wash thoroughly after handling. Avoid dusting when handling and avoid all possible sources of ignition (spark or flame). |
| Respiratory Protection | None required with normal handling of finished product. |
| Additional Protective Equipment | No special recommendations. |

## 9. Physical and Chemical Properties

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|---|---|
| Appearance | Blue, modified apple-shaped, film-coated tablets. |
| Odor/Threshold Limit | Odorless. |
| pH | Not available. |
| Boiling Point | Not applicable. |
| Melting Point | **FINASTERIDE**: 252 to 254°C (485.6 to 489.2°F) |
| Flash point | Not applicable. |
| Flammable Limits (% in air) | Not applicable. |
| Autoignition Temperature | Not relevant under normal conditions of product handling. |
| Solubility | **FINASTERIDE**: Very slightly soluble in cold water |
| Partition Coefficient | **FINASTERIDE**: Log Kow: 3.5 |
| Specific Gravity | Not applicable. |
| Vapor Density | Not applicable. |
| Vapor Pressure | Not applicable. |
| Volatility Component | 0% (w/w). |

## 10. Stability and Reactivity

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|---|---|
| Stability | The product is stable. |
| Conditions to Avoid | Avoid temperatures above 30ºC (86ºF). |
| Incompatibility | None known. |
| Hazardous Polymerization | Will not occur. |
| Hazardous Decomposition Products | These products are carbon oxides, nitrogen oxides. |

## 11. Toxicological Information

| | | |
|---|---|---|
| Routes of Entry | Ingestion: | No. |
| | Inhalation: | Yes. |
| | Skin Contact: | No. |

Toxicity Data

| Component | Test | Species | Route | Result |
|---|---|---|---|---|

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| | | | | |
|---|---|---|---|---|
| FINASTERIDE | LD50 | Rat (F) | Oral | 373 mg/kg |
| | LD50 | Rat (M) | Oral | 828 mg/kg |
| | LD50 | Mouse (F) | Oral | 486 mg/kg |
| | Irrit. | Rabbit | Dermal | Non-irritating |
| | Irrit. | Rabbit | Ocular | Slightly irritating |

Effects of Acute Exposure

Eye contact — No data available for the finished product.
**FINASTERIDE:** Severely irritating to eyes.

Skin contact — Not available.

Inhalation — None expected with handling of finished product. Exposure to crushed tablets may cause irritation.

Ingestion — Intended route for clinical use. Not intended for ingestion by women.

Effects of Chronic Exposure — Contains material which may cause birth defects based on animal data.

**FINASTERIDE**: Finasteride is used to treat symptomatic benign prostatic hyperplasia and male pattern hair loss in men.

Women that are or may be pregnant should strictly avoid inhalation or skin contact. Reproductive effects observed in male rats when administered orally before mating.

Generally not mutagenic. However, finasteride tested positive for mutagenicity in one study at high doses. Non-carcinogenic in mice and rats. Benign testicular tumors were found in high dose mouse studies. These testicular effects were not seen in rats and dogs.

Adverse reactions with clinical use include breast tenderness and enlargement, lip swelling and skin rash. Side effects noted in less than 4% of patients in clinical studies include impotence, decreased libido and volume of ejaculate.

Carcinogen Designation — Not listed as a carcinogen by OSHA, NTP or IARC.

Medical Conditions Aggravated by Overexposure: — **FINASTERIDE**: Individuals with liver function abnormalities.

## 12. Ecological Information

Environmental Effects — **FINASTERIDE**: Finasteride is harmful to aquatic organisms and may interfere with testosterone metabolism in fish. Finasteride will not inhibit the organisms of an activated sludge sewage treatment at concentrations less than or equal to 50 mg/L. Finasteride may cause long-term adverse effects in the aquatic environment.

Ecotoxicity Data

| Component | Species | Period | Result |
|---|---|---|---|
| FINASTERIDE | *Daphnia magna* (LC50) | 48 hour(s) | 21 mg/L |
| | Rainbow Trout (LC50) | 96 hour(s) | 19.6 mg/L |

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Environmental Fate

**FINASTERIDE**: The Log Kow of 3.5 suggests that Finasteride has the potential to bioaccumulate and to persist. However data from a study with the green alga Selenastrum capricornutum also indicates that some biotransformation to inactive components is possible.

## 13. Disposal Considerations

Waste Disposal Information

Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spills residues including contaminated soils following all federal, state, or local regulations.

## 14. Transport Information

Shipping Description

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|---|---|
| U.S. DOT | Not regulated. |
| IATA/ICAO | Not regulated. |
| IMO | Not regulated. |
| ADR/RID | Not regulated. |

## 15. Regulatory Information

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|---|---|
| U.S. Federal Regulations | Exempt from OSHA Hazard Communication Standard. |
| State Regulations | Not applicable. |
| International Regulations | Exempt from the EU Dangerous Substances Directive. |

## 16. Other Information

Revisions: Intended use; Emergency Overview; First Aid Measures; Accidental Release Measures; Handling and Storage; Effects of Acute Exposure Ingestion; Effects of Chronic Exposure; Medical Conditions Aggravated by Overexposure

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|---|---|
| Date of Preparation | 04-Nov-2004 |
| Date of Previous Issue | 04-Nov-2004 |
| Validation Date | 12/21/2005. |
| MSDS Coordinator: | 1-908-423-7903<br>Merck & Co., Inc.<br>Two Merck Drive<br>P.O. Box 200, WS2W-13<br>Whitehouse Station, NJ 08889-0200<br>U.S.A. |

Disclaimer:

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