

# SAFETY DATA SHEET

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

**Product identifier:****Product name:** Finasteride Tablets (5 mg)**SDS No:** P00000020014**Synonyms, Trade Names:** FINASTERIDE FROSST, CHIBRO-PROSCAR, FINASPROS, GENAPROST, FINASTID, PRO-CURE, PROSTIDE, URPROSAN, MK-0906 Tablets (5 Mg)**Additional identification:****Class:** Type II 5 alpha-reductase inhibitor Type II 5 alpha-reductase inhibitor**Chemical name:** Active pharmaceutical ingredient: N-(1,1-Dimethylethyl)-3-oxo-4-aza-5 $\alpha$ -androst-1-ene-17 $\beta$ -carboxamide (CAS Style name)**Relevant identified uses of the substance or mixture and uses advised against:****Identified uses:** Finished pharmaceutical product: Indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH).**Uses advised against:** Intended for men only.**Details of the supplier of the safety data sheet:****Manufacturer:**MSD  
Kilsheelan  
Clonmel Tipperary, IE**Telephone:** 353-51-601000**e-mail:** MSDS@merck.com**Emergency telephone number:** 1-908-423-6000 (24/7/365) English Only**Emergency telephone number:** EU Transportation Emergencies - Carechem24: +44 (0)208 762 8322 (24 hours/7 days/week)

## SECTION 2: Hazards identification

**Classification of the substance or mixture:**

The product has been classified according to the legislation in force.

**Classification according to Directive 67/548/EEC or 1999/45/EC as amended:**

T; R48/25 Repr. 1; R60 R61 N; R51/53

**Classification according to Regulation (EC) No 1272/2008 as amended:****Health hazards:**

Toxic to reproduction	Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure	Category 1	H372: Causes damage to organs through prolonged or repeated exposure: prostate.

**Environmental hazards:**

Chronic hazards to the aquatic environment

Category 2

H411: Toxic to aquatic life with long lasting effects.

**Hazard summary:**

**Physical hazards:** None expected with normal handling of finished product. Avoid conditions which create dust.

**Health hazards:**

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

**Eye contact:** No specific hazard with intact tablets or capsules.

**Skin contact:** No specific hazard with intact tablets or capsules. Avoid contact with skin.

**Ingestion:** Intended route for clinical use.

**Other Health Effects:** AVOID EXPOSURE TO CRUSHED OR BROKEN TABLETS IF YOU ARE OR MIGHT BE PREGNANT.

**Environmental hazards:** Toxic to aquatic life with long lasting effects.

**Label elements:**

**Contains:** FINASTERIDE



**Signal words:** Danger

**Hazard Statement(s):** H372: Causes damage to organs through prolonged or repeated exposure: prostate gland.  
 H360FD: May damage fertility. May damage the unborn child.  
 H411: Toxic to aquatic life with long lasting effects.

**Precautionary statement:**

**Prevention:** P202: Do not handle until all safety precautions have been read and understood.  
 P260: Do not breathe dust.  
 P273: Avoid release to the environment.  
 P281: Use personal protective equipment as required.  
 P264: Wash thoroughly after handling.  
 P270: Do not eat, drink or smoke when using this product.  
 P201: Obtain special instructions before use.

**Response:** P308+P313: IF exposed or concerned: Get medical advice/attention.  
 P391: Collect spillage.

**Disposal:** P501: Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

**Other hazards:** None known.

**SECTION 3: Composition/information on ingredients**

**Mixtures:**

**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.

Chemical name	Concentration	CAS-No.	EC No.	REACH Registration No.	Notes
FINASTERIDE	3,25%	98319-26-7			

\* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.  
This substance has workplace exposure limit(s).  
PBT: persistent, bioaccumulative and toxic substance.  
vPvB: very persistent and very bioaccumulative substance.

**Classification:**

Chemical name	Classification		Notes
FINASTERIDE	DPD:	Xn; R22 Repr. 1; R60, R61 T; R48/25 N; R52/53	
	CLP:	Acute Tox. 4;H302, Repr. 1B;H360FD, STOT RE 1;H372, Aquatic Chronic 1;H410	

DPD: Directive 67/548/EEC.  
CLP: Regulation No. 1272/2008.:

The full text for all R & H -phrases is displayed in section 16.

**SECTION 4: First aid measures**

**Description of first aid measures:**

- Inhalation:** Move to fresh air. For breathing difficulties, oxygen may be necessary. If breathing stops, provide artificial respiration. Get medical attention.
- 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.
- Skin contact:** Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing.
- Ingestion:** Do not induce vomiting. Get medical attention if symptoms occur.

**Most important symptoms and effects, both acute and delayed:** May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure: prostate. In clinical use, the most serious adverse reactions include: breast tenderness and enlargement, lip swelling, skin rash, impotence, decreased libido and volume of ejaculate.

**Indication of any immediate medical attention and special treatment needed:**

- Hazards:** See Sections 2 and 11.
- Treatment:** Treat supportively and symptomatically.

**SECTION 5: Firefighting measures**

**General fire hazards:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

<b>Extinguishing media:</b>	
<b>Suitable extinguishing media:</b>	Water spray, fog, CO <sub>2</sub> , dry chemical, or alcohol resistant foam.
<b>Unsuitable extinguishing media:</b>	None known.
<b>Special hazards arising from the substance or mixture:</b>	Emits toxic fumes under fire conditions.
<b>Advice for firefighters:</b>	
<b>Special Fire Fighting Procedures:</b>	No data available.
<b>Special protective equipment for fire-fighters:</b>	Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

### SECTION 6: Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures:</b>	Use personal protective equipment. Keep unnecessary personnel away.
<b>Environmental precautions:</b>	Do not release into the environment.
<b>Methods and material for containment and cleaning up:</b>	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.

### SECTION 7: Handling and storage:

<b>Precautions for safe handling:</b>	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.
<b>Conditions for safe storage, including any incompatibilities:</b>	Keep container tightly closed in a cool, well-ventilated place.
<b>Specific end use(s):</b>	Pharmaceutical preparation.

### SECTION 8: Exposure controls/personal protection

#### Control parameters:

#### Occupational exposure limits:

Chemical name	Type	Exposure Limit values	Source
FINASTERIDE	TWA	0.5 ug/m <sup>3</sup> (OEB 5)	Merck
	Wipe Limit	5 ug/100 cm <sup>2</sup>	Merck

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

#### Exposure controls:

**Appropriate engineering controls:** 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.

**Individual protection measures, such as personal protective equipment:**

**General information:** Reference: Directive 89/686/EEC. Observe occupational exposure limits and minimize the risk of inhalation of dust.

**Eye/face protection:** Reference standard: EN 166. If contact is likely, safety glasses with side shields are recommended.

**Skin protection:**  
**Hand protection:** Reference standard: EN 374. Disposable chemical resistant gloves wherever the potential exists for direct exposure to residual dust from crushed or broken tablets or capsules.

**Other:** Work uniform or laboratory coat when there is potential for direct contact with the residual dust from crushed or broken tablets.

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

**Hygiene measures:** Wash skin thoroughly with soap and water.

**Environmental Controls:** No data available.

## **SECTION 9: Physical and chemical properties**

**Information on basic physical and chemical properties:**

**Appearance:**

<b>Physical State:</b>	Solid
<b>Form:</b>	Tablets
<b>Color:</b>	Blue
<b>Odor:</b>	Odorless
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	This product is not flammable.
<b>Flammability Limit - Upper (%)-:</b>	No data available.
<b>Flammability Limit - Lower (%)-:</b>	No data available.
<b>Vapor pressure:</b>	No data available.
<b>Vapor density (air=1):</b>	No data available.
<b>Relative density:</b>	No data available.
<b>Solubility(ies):</b>	
<b>Solubility in Water:</b>	No data available.
<b>Solubility (other):</b>	No data available.
<b>Partition coefficient (n-octanol/water):</b>	3,5 Active Pharmaceutical Ingredient. Log Kow at pH 7

<b>Autoignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.
<b>Explosive properties:</b>	No data available.
<b>Oxidizing properties:</b>	No data available.
<b>Other information:</b>	
<b>VOC Content:</b>	0 g/l

### **SECTION 10: Stability and reactivity**

<b>Reactivity:</b>	No data available.
<b>Chemical stability:</b>	Stable
<b>Possibility of hazardous reactions:</b>	Stable
<b>Conditions to avoid:</b>	Moisture. Excessive heat.
<b>Incompatible materials:</b>	None under normal conditions.
<b>Hazardous decomposition products:</b>	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

### **SECTION 11: Toxicological information**

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

#### **Information on likely routes of exposure**

<b>Inhalation:</b>	No specific hazard with intact tablets or capsules. Avoid breathing dust.
<b>Ingestion:</b>	Intended route for clinical use.
<b>Skin contact:</b>	No specific hazard with intact tablets or capsules. Avoid contact with skin.
<b>Eye contact:</b>	No specific hazard with intact tablets or capsules.

#### **Information on toxicological effects:**

##### **Acute Toxicity:**

###### **Oral:**

**Product:** No data available.

###### **Specified substance(s):**

FINASTERIDE  
LD50 (Rat): 373 mg/kg  
LD50 (Rat): 828 mg/kg  
LD50 (Mouse): 486 mg/kg

###### **Dermal:**

**Product:** No data available.

###### **Specified substance(s):**

FINASTERIDE No data available.

<b>Inhalation:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	No data available.
<b>Repeated dose toxicity:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
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.
<b>Skin corrosion/irritation:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	Dermal Irritation (Rabbit): Non-Irritating
<b>Serious eye damage/eye irritation:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	Ocular Irritation (Rabbit): Slightly irritating
<b>Respiratory or skin sensitization:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	No data available.
<b>Germ cell mutagenicity:</b>	
<b>In vitro:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	Negative in a battery of in vitro genotoxicity assays.
<b>In vivo:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	Negative in a battery of in vivo genotoxicity assays.
<b>Carcinogenicity:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	
FINASTERIDE	Benign testicular tumors were observed in mice. Not listed as carcinogen by OSHA, NTP or IARC.
<b>Reproductive toxicity:</b>	
<b>Product:</b>	No data available.
<b>Specified substance(s):</b>	

FINASTERIDE

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

**Specific target organ toxicity - single exposure:****Product:** No data available.**Specific target organ toxicity - repeated exposure:****Product:** Causes damage to organs through prolonged or repeated exposure: prostate.**Aspiration hazard:****Product:** Not applicable**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.

**SECTION 12: Ecological information****General information:**

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

**Ecotoxicity:****Acute toxicity:****Fish:****Product:** No data available.**Specified substance(s):**FINASTERIDE LC50 (Rainbow Trout (*Oncorhynchus mykiss*), 96 h): 19,6 mg/l**Aquatic invertebrates:****Product:** No data available.**Specified substance(s):**FINASTERIDE LC50 (Water flea (*Daphnia magna*), 48 h): 21 mg/l  
NOEC (Water flea (*Daphnia magna*), 48 h): 5,3 mg/l**Chronic Toxicity:****Fish:****Product:** No data available.**Specified substance(s):**

FINASTERIDE No data available.

**Aquatic invertebrates:****Product:** No data available.**Specified substance(s):**FINASTERIDE LOEC (Water flea (*Daphnia magna*), 21 d): 0,3 mg/l  
NOEC (Water flea (*Daphnia magna*), 21 d): 0,12 mg/l**Toxicity to Aquatic Plants:****Product:** No data available.**Specified substance(s):**FINASTERIDE NOEC (Green algae (*Selenastrum capricornutum*), 14 d): 49 mg/l



**Persistence and degradability:****Biodegradation:****Product:** No data available.**Specified substance(s):**

FINASTERIDE Not readily biodegradable

**BOD/COD ratio:****Product:** No data available for finished product.**Bioaccumulative potential:****Product:** No data available.**Specified substance(s):**

FINASTERIDE Not likely to bioaccumulate based on log Kow

**Mobility in soil:**

No data available for finished product.

**Results of PBT and vPvB assessment:**

No data available.

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Not expected to be a PBT or vPvB compound.

**Other adverse effects:**

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

**SECTION 13: Disposal considerations****Waste treatment methods:****General information:**

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.

**Disposal Methods:**

Do not allow runoff to sewer, waterway or ground. Discharge, treatment, or disposal may be subject to national, state, or local laws.

**SECTION 14: Transport information****ADR/RID**

Not regulated.

**IMDG**

Not regulated.

**IATA - International Air Transport Association**

Not regulated.

**Environmental hazards:**

Not regulated.

**Special precautions for user:**

None known.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.**SECTION 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture:**

**EU Regulations:**

**Regulation (EC) No. 2037/2000 Substances that deplete the ozone layer:** None

**Regulation (EC) No. 850/2004 on persistent organic pollutants:** None

**Regulation (EC) No. 689/2008 Import and export of dangerous chemicals:** None

**Regulation (EC) No. 1907/2006 Annex XIV Substance subject to authorisation:** None

**Regulation (EC) No. 1907/2006 Annex XVII Substances subject to restriction on marketing and use:**  
None

**Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens and mutagens at work:** None

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breast feeding.:** None

**Directive 96/61/EC: concerning integrated pollution prevention and control (IPPC): Article 15, European Pollution Emission Registry (EPER):** None

**Directive 96/82/EC (Seveso II): on the control of major accident hazards involving dangerous substances:** None

**Directive 98/24/EC on the protection of workers from the risks related to chemical agents at work.:** None

**National Regulations:**

Not applicable

**Chemical safety assessment:** No data available.

**SECTION 16: Other information****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  
SECTION 16: Other information

**Key literature references and sources for data:**

Compiled in accordance with Regulation (EU) No. 453/2010.  
Safety assessment reports, investigator brochures and/or product circulars.  
Supplier provided safety data sheet  
Glossary of abbreviations:  
CAS - Chemical Abstract Service  
HEPA - High Efficiency Particulate Arresting  
SCBA - Self Contained Breathing Apparatus  
TWA - Time weighted average

**Wording of the R-phrases and H-statements in section 2 and 3:**

H302	Harmful if swallowed.
H360FD	May damage fertility. May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
R22	Harmful if swallowed.
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R60	May impair fertility.
R61	May cause harm to the unborn child.

**Training information:** Consult your supervisor or local safety & health professional for required training appropriate for the safe handling, use of protective equipment, and emergency response for this material.

**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.

**Issue Date:** 09.05.2013

**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.