

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## FINASTERIDUM

EN

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Publication: 25/03/2022

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Finasteride Finasteridum Finasteride Finastéride Finasterid
N° CAS:	98319-26-7
N° EC:	620-534-3

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Repr. 1B	H360
STOT RE 1	H372
Aquatic Chronic 1	H410

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention, Irritant, Harmful

Hazard statements:

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H302	Harmful if swallowed.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements:	
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash face, hands and any exposed skin thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with soap and water.
P305+P351+P338	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing, and seek medical active.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Finasteride
IUPAC name:	N-(1,1-Dimethylethyl)-3-oxo-4-aza-5 $\alpha$ -androst-1-ene-17 $\beta$ -carboxamide
Synonyms:	Proscar Propecia
N° CAS:	98319-26-7
N° EC:	620-534-3
Molecular Formula:	C <sub>23</sub> H <sub>36</sub> N <sub>2</sub> O <sub>2</sub>
Content:	98.0 per cent to 102.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	In case of contact with the substances, immediately change contaminated clothing, consult a physician and show this sheet.
After inhalation:	Remove casualty to fresh air as quickly as possible. Keep warm and at rest. If breathing is difficult, give oxygen if possible, or assisted ventilation.
After skin contact:	In case of skin contact with powders or solutions immediately rinse affected area with copious amount of water and then wash with soap and water. Remove contaminated clothing and shoes.
After eye contact:	

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After ingestion:

Irrigate eyes with copious amounts of water for at least 10-15 min, holding eyelids apart to ensure thorough rinsing.

In case of ingestion, if conscious, rinse mouth with water. If the casualty is unconscious, place in the recovery position.

### 4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Thus, no indication on both acute and delayed effects is available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Obtain medical assistance if breathing remains difficult. Induce vomiting only if indicated by your doctor.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:

Carbon dioxide (CO<sub>2</sub>), foam, dries chemical powder, water spray, and water jet, unless otherwise stated.

Unsuitable extinguishing media:

None.

### 5.2 Special hazards arising from the substance/mixture

Not available.

### 5.3 Advice for firefighters

Surrounding fires:

Ensure the availability of equipment for cooling containers to prevent the danger of overheating in the event of a fire nearby.

Protection against fire:

Wear full fire resistant self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Keep non-involved personnel away from the area of spillage. Avoid the generation and spreading of dust. Ventilate area. Eliminate sources of ignition. Avoid contact with skin, eyes and inhalation of dust.

#### For emergency responders

Keep non-involved personnel away from the area of spillage. Avoid the generation and spreading of dust. Ventilate area. Eliminate sources of ignition. Avoid contact with skin, eyes and inhalation of dust.

### 6.2 Environmental precautions

Prevent product from entering sewers, rivers or other bodies of water.

If required, notify relevant authorities according to all applicable regulations.

### 6.3 Methods and material for containment and cleaning up

Collect free product with suitable mechanical means.

Avoid creating dust, if there is no contraindication.

Ventilate area and wash spill site after material pickup is complete.

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Transfer the gathered product and the washings to suitable tanks or containers and store/dispose according to relevant regulations.

### 6.4 Reference to other sections

See also sections 8 (protective equipment) and 13 (disposal).

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Use of personal protective equipment must be consistent with good occupational hygiene practices. Avoid contact with skin, eyes and clothing. Avoid prolonged or repeated exposure. Do not breathe dust. Do not reuse contaminated clothing. Do not eat, drink or smoke when using this product.
Personal protection:	Use of personal protective equipment must be consistent with good occupational hygiene practices.
Technical protective measures:	Not available.
Handling:	Wash hands thoroughly with soap and water before meals and after work shift.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Store at room temperature. Keep container tightly closed in a cool, well ventilated place.
Storage – away from:	Store away from all heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Exposure limit values (ACGIH 2010): Not available.  
Monitoring procedures: Refer to Dir. 96/82/EC.

### 8.2 Exposure controls

#### Appropriate engineering control

When feasible, use closed loop systems or with local exhaust. When inside buildings or confined spaces, ensure adequate ventilation. The lyophilized powder should be used in biological safety cabinets or in systems with equivalent content. Provide eyewash fountains at the workplace.

#### Individual protection measures

Eye/face protection:	Wear safety goggles (EN 166).
Skin protection:	Protective clothing global.

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The personal protective equipment should be chosen in the configuration according to the concentration and quantity of hazardous substances specifically for the workplace.

Hand protection: Use rubber or synthetic gloves (EN 374).

Respiratory protection: Avoid inhalation of dust, respiratory protection: dust mask with filter type P3 (EN 143). When required, use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards: The product is not handled hot.

### Environmental exposure control

Use according to good manufacturing practices avoiding litter. Take all the technical precautions necessary to prevent the spread of the product into the surrounding.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Non-flammable.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol and in methylene chloride.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

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Specific rotation: +12° ~ 14° in methanol R.

### SECTION 10: STABILITY AND REACTIVITY

#### 10.1 Reactivity

The substance does not present additional dangers of reactivity than those reported in the next subtitles.

#### 10.2 Chemical stability

The substance is stable in normal conditions of temperature and pressure. Store away from all heat sources, including direct sunlight, open flame, sources of ignition and sparks.

#### 10.3 Possibility of hazardous reactions

Product does not polymerise.

#### 10.4 Conditions to avoid

Heat, flames, source of ignition, and static electricity.

#### 10.5 Incompatible materials

Store separately from oxidizing agents.

#### 10.6 Hazardous decomposition products

When heated or in the event of a fire, vapors may be harmful to health: Carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>).

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	No reported evidence concerning this effect.
Skin corrosion/irritation:	May cause skin irritation.
Serious eye damage/irritation:	May cause eye irritation.
Respiratory/skin sensitisation:	No reported evidence concerning this effect.
Germ cell mutagenicity:	No reported evidence concerning this effect.
Carcinogenicity:	No reported evidence concerning this effect.
Reproductive toxicity:	No reported evidence concerning this effect.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	The product may cause mild irritation of the mucous membranes and upper respiratory tract.
STOT-repeated exposure:	No reported evidence concerning this effect.
Aspiration Hazard:	Not applicable.
Other:	Signs and symptoms of exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

#### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.

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Ingestion: Harmful if swallowed.

Aspiration: Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Not available.

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

#### 12.6 Other adverse effects

Very toxic to aquatic life with long lasting effects.

### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Dispose of spills in a chemical waste system and bury in approved landfill according to local regulations. The waste solid and/or liquid materials should be burnt out in an incinerator.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

##### 14.5 Environmental hazards

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ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

### 14.6 Special precautions for user

Not available.

### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

### 14.8 Additional transport information

During in storage and transporting, keep it in closed container. Away from direct sunlight, heat and humidity, and handle it with care, in case the inner-bag broken.

## SECTION 15: REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Irritant  
Harmful

Risk phrases:

R21/22 Harmful in contact with skin and if swallowed.  
R36/38 Irritating to eyes and skin.  
R48 Danger of serious damage to health by prolonged exposure.  
R50/53 Very 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.

Safety phrases:

S20/21 When using do not eat, drink or smoke.  
S23 Do not breathe dust/fume/gas/mist/vapours/spray.  
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.  
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
S28 After contact with skin, wash immediately with plenty of soap and water.

### 15.2 Chemical safety assessment

Not available.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road  
CAS: Chemical Abstracts Service (division of the American Chemical Society)



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EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available.

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

Quality Department

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