

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

- **1.1 Product identifier**
- **Trade name:** Finasteride (Form III)  
Finasteridum
- **Article number:** 101588
- **CAS Number:**  
98319-26-7
- **EC number:**  
620-534-3
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

Acute Tox. 4	H302 Harmful if swallowed.
Repr. 1B	H360 May damage fertility or the unborn child.
STOT RE 1	H372 Causes damage to organs through prolonged or repeated exposure.
Aquatic Chronic 1	H410 Very toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**



GHS07 GHS08 GHS09

· **Signal word** Danger

· **Hazard statements**

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.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

· **3.1 Chemical characterisation: Substances**

· **CAS No. Description**

98319-26-7 Finasteride (Form III)

Finasteridum

· **Identification number(s)**

· **EC number:** 620-534-3

## SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** Call for a doctor immediately.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## **SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
Water spray  
Alcohol resistant foam  
Fire-extinguishing powder  
Carbon dioxide  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
Nitrogen oxides (NO<sub>x</sub>)  
Carbon monoxide (CO)
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

## **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

## **SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.

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- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Store protective clothing separately.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

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

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· <b>Form:</b>	Crystalline powder
· <b>Colour:</b>	White
· <b>Odour:</b>	Recognisable
· <b>Odour threshold:</b>	Not determined.
- **pH-value:** Not applicable.

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· <b>Change in condition</b> Melting point/freezing point: Initial boiling point and boiling range:	Undetermined. Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Product is not flammable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Not determined.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b> Lower: Upper:	Not determined. Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density:</b> · <b>Relative density</b> · <b>Vapour density</b> · <b>Evaporation rate</b>	Not determined. Not determined. Not applicable. Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> Dynamic: Kinematic:	Not applicable. Not applicable.
· <b>9.2 Other information</b>	No further relevant information available.

## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
Carbon monoxide and carbon dioxide  
Nitrogen oxides (NO<sub>x</sub>)

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

Harmful if swallowed.

#### LD/LC50 values relevant for classification:

Oral	LD50	418 mg/kg (rat)
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#### Primary irritant effect:

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**  
May damage fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**  
Causes damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1 Toxicity

- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

#### Additional ecological information:

#### General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Danger to drinking water if even extremely small quantities leak into the ground.  
Also poisonous for fish and plankton in water bodies.

#### 12.5 Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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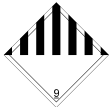


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· <b>European waste catalogue</b>	
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP6	Acute Toxicity
HP10	Toxic for reproduction
HP14	Ecotoxic

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

· <b>14.1 UN-Number</b> · <b>ADR, IMDG, IATA</b>	UN3077
· <b>14.2 UN proper shipping name</b> · <b>ADR</b>  · <b>IMDG</b>  · <b>IATA</b>	3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride (Form III) Finasteridum) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride (Form III) Finasteridum) Environmentally hazardous substance, solid, n.o.s. (Finasteride (Form III) Finasteridum)
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, IATA</b>	
 	
· <b>Class</b> · <b>Label</b>	9 Miscellaneous dangerous substances and articles. 9
· <b>IMDG</b>	
	
· <b>Class</b> · <b>Label</b>	9 Miscellaneous dangerous substances and articles. 9

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· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards: · Special marking (ADR): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
· 14.6 Special precautions for user  · Hazard identification number (Kemler code): · EMS Number: · Stowage Category · Stowage Code	Warning: Miscellaneous dangerous substances and articles. 90 F-A,S-F A SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· Transport category · Tunnel restriction code	3 -
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FINASTERIDE (FORM III) FINASTERIDUM), 9, III

## SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I Substance is not listed.
- Seveso category E1 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II  
Substance is not listed.

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- **REGULATION (EU) 2019/1148**
- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**  
Substance is not listed.
- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## **SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Fagron Česká republika
- **Contact:** msds@fagron.cz
- **Abbreviations and acronyms:**  
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Acute Tox. 4: Acute toxicity – Category 4  
Repr. 1B: Reproductive toxicity – Category 1B  
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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