SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Finasteride (3.25%) Formulation

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

1.1 Product identifier
Trade name : Finasteride (3.25%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Innishannon
County Cork - Ireland

Telephone : 353 214329300
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated exposure, Category 2
Long-term (chronic) aquatic hazard, Category 2
H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

 Signal word : Danger

Hazard statements :
H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
Finasteride

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finasteride</td>
<td>98319-26-7</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Repr. 1B; H360D STOT RE 1; H372 Aquatic Chronic 1; M-Factor (Chronic aquatic toxicity): 1</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
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If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks : May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides

5.3 Advice for firefighters
Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing method : Use extinguishing measures that are appropriate to local cir-
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye
flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
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<tr>
<td>Further information</td>
<td>Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m³</td>
<td>IE OEL</td>
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<tr>
<td>Further information</td>
<td>Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhalable dust)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Finasteride</td>
<td>98319-26-7</td>
<td>TWA</td>
<td>0.5 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>5 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**Engineering measures**

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

Eye protection:

- Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection:

- Material: Chemical-resistant gloves
- Remarks: Consider double gloving.

Skin and body protection:

- Material: Work uniform or laboratory coat.
- Remarks: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Remarks: Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection:

- Filter type: Particulates type (P)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

- Appearance: solid
- Colour: blue
- Odour: odourless
- Odour Threshold: No data available
- pH: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point: Not applicable
- Evaporation rate: Not applicable
- Flammability (solid, gas): Not classified as a flammability hazard
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : No data available
   Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
   Flammability (liquids) : No data available
   Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
   Not classified as a reactivity hazard.

10.2 Chemical stability
   Stable under normal conditions.

10.3 Possibility of hazardous reactions
   Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
   Conditions to avoid : None known.

10.5 Incompatible materials
   Materials to avoid : Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:
- Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
  Method: Calculation method

Components:

Finasteride:
- Acute oral toxicity: LD50 (Rat): 373 - 828 mg/kg
- LD50 (Mouse): 486 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Finasteride:
- Species: Rabbit
- Result: No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Finasteride:
- Species: Rabbit
- Remarks: slight irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Germ cell mutagenicity
Not classified based on available information.

Components:

Finasteride:
Genotoxicity in vitro:
Test Type: Chromosome aberration test in vitro
Result: positive

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Alkaline elution assay
Result: negative

Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Finasteride:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
160 mg/kg body weight
Result: negative
Target Organs: Testes
Remarks: Benign tumor(s)

Species: Mouse
Application Route: Ingestion
Exposure time: 19 month(s)
Result: negative
Target Organs: Testes
Remarks: Benign tumor(s)

Reproductive toxicity
May damage the unborn child.

Components:

Finasteride:
Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 80 mg/kg body weight
Result: No effects on fertility

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Fertility: LOAEL: 80 mg/kg body weight
Result: positive
Remarks: There is no evidence that these findings are relevant to humans.

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Developmental Toxicity: LOAEL: 0.003 mg/kg body weight
Result: Teratogenic effects, Embryotoxic effects.

Test Type: Embryo-foetal development
Species: Monkey
Application Route: Ingestion
Developmental Toxicity: LOAEL: 2 mg/kg body weight
Result: Teratogenic effects

Reproductive toxicity - Assessment:
Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Finasteride:

Exposure routes:
Ingestion

Target Organs:
Testis

Assessment:
Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Finasteride:

Species:
Rat

NOAEL:
20 mg/kg

LOAEL:
40 mg/kg

Application Route:
Oral

Exposure time:
1 yr

Target Organs:
Testis

Species:
Dog

NOAEL:
45 mg/kg

Application Route:
Oral
Exposure time: 1 yr  
Target Organs: Testis

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**Finasteride:**

Ingestion: Symptoms: breast tenderness, breast enlargement, impotence, lip swelling, skin rash

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Finasteride:**

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 20.4 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 17.8 mg/l  
Exposure time: 48 h  
Method: FDA 4.08

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 49 mg/l  
Exposure time: 14 h  
Method: FDA 4.01

Toxicity to fish (Chronic toxicity): NOEC: 0.05 mg/l  
Exposure time: 105 d  
Species: Oryzias latipes (Orange-red killifish)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 0.12 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1

**12.2 Persistence and degradability**

**Components:**

**Finasteride:**

Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 0%  
Exposure time: 7 d
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12.3 Bioaccumulative potential

Components:

Finasteride:
Partition coefficient: n-octanol/water: log Pow: 3.57

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
ADN: UN 3077
ADR: UN 3077
RID: UN 3077
IMDG: UN 3077
IATA: UN 3077

14.2 UN proper shipping name
ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride)
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RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride)

IATA : Environmentally hazardous substance, solid, n.o.s. (Finasteride)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
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Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN  Environmentally hazardous : yes
ADR  Environmentally hazardous : yes
RID  Environmentally hazardous : yes
IMDG  Marine pollutant : yes
IATA (Passenger)  Environmentally hazardous : yes
IATA (Cargo)  Environmentally hazardous : yes

14.6 Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable. 
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

- H302: Harmful if swallowed.
- H360D: May damage the unborn child.
- H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
- H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Acute Tox.: Acute toxicity
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure
- IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisa-
Finasteride (3.25%) Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>2.2</td>
<td>09/13/2019</td>
<td>2161033-00006</td>
<td>24.04.2019</td>
<td>09.11.2017</td>
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Further information


Classification of the mixture:

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<tr>
<th>Classification procedure:</th>
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<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
</tr>
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</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IE / EN