SAFETY DATA SHEET

Finasteride (3.25%) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Finasteride (3.25%) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Testis)
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements: H360D May damage the unborn child.
H373 May cause damage to organs (Testis) through prolonged or repeated exposure if swallowed.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P273 Avoid release to the environment.
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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.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Finasteride</td>
</tr>
</tbody>
</table>

4. 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.

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.

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

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).
5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Metal oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- 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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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 breathe dust, fume, gas, mist, vapours or spray.
- Do not swallow.
- Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA</td>
<td>ACGIH</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></td>
<td>Wipe limit 5 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

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

Respiratory protection:
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - Filter type: Particulates type

Hand protection:
- Material: Chemical-resistant gloves
Remarks

Consider double gloving.

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.

Skin and body protection

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

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.

9. 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

Flammability (liquids)

No data available

Upper explosion limit / Upper flammability limit

No data available

Lower explosion limit / Lower flammability limit

No data available
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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.
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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:
Cellulose:
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</table>

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**Starch:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**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

**Starch:**
Species : Rabbit
Result : No eye irritation

**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.

**Components:**

**Starch:**
Test Type : Maximisation Test
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</tbody>
</table>

**Exposure routes**: Skin contact

**Species**: Guinea pig

**Result**: negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Cellulose:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: negative

#### Starch:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

#### 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:

#### Cellulose:

- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 72 weeks
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</tbody>
</table>

**Result:** negative

### Finasteride:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td></td>
<td>160 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testes</td>
</tr>
<tr>
<td>Remarks</td>
<td>Benign tumor(s)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>19 month(s)</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Testes</td>
</tr>
<tr>
<td>Remarks</td>
<td>Benign tumor(s)</td>
</tr>
</tbody>
</table>

### Reproductive toxicity

May damage the unborn child.

### Components:

#### Cellulose:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative</th>
</tr>
</thead>
</table>

#### Finasteride:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development Species: Rabbit Application Route: Oral Fertility: NOAEL: 80 mg/kg body weight Result: No effects on fertility</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>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.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Developmental Toxicity: LOAEL: 0.003 mg/kg body weight</th>
</tr>
</thead>
</table>
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 (Testis) through prolonged or repeated exposure if swallowed.

Components:

Finasteride:
Exposure routes: Ingestion
Target Organs: Testis
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

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

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Cellulose:**
Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)) : > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

**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 (Oryzias latipes (Orange-red killifish)) : 0.05 mg/l
Exposure time: 105 d

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

M-Factor (Chronic aquatic toxicity) : 1

**Persistence and degradability**

**Components:**

**Cellulose:**
Biodegradability : Result: Readily biodegradable.
Finasteride: Biodegradability: Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 7 d Method: FDA 3.11

Stability in water: Hydrolysis: 0 % (5 d) Method: FDA 3.09

Bioaccumulative potential

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

Mobility in soil: No data available

Other adverse effects: No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride)

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Finasteride)

Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
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- **Packing instruction (passenger aircraft)**: 956
- **Environmentally hazardous**: yes

**IMDG-Code**
- **UN number**: UN 3077
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Finasteride)

**Class**: 9  
**Packing group**: III  
**Labels**: 9  
**EmS Code**: F-A, S-F  
**Marine pollutant**: yes

*Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code*

Not applicable for product as supplied.

**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.

### 15. REGULATORY INFORMATION

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

  - Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.
  
  - Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
    - Hazardous substances that must be registered: Not applicable
  
  - Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
    - Hazardous substances approved for use: Not applicable
    - Prohibited substances: Not applicable
    - Restricted substances: Not applicable
  
  - Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
    - Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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

- **AICS**: not determined
16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average

ID OEL / NAB: Long term exposure limit

DSL: not determined
IECSC: not determined

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.

ID / EN