1. PRODUCT AND COMPANY IDENTIFICATION

   Chemical product name : Finasteride (1%) Formulation

   Supplier’s company name, address and phone number
   Company name of supplier : Organon & Co.
   Address : 30 Hudson Street, 33nd floor
              Jersey City, New Jersey, U.S.A 07302
   Telephone : 551-430-6000
   E-mail address : EHSSTEWARD@organon.com
   Emergency telephone number : 215-631-6999

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

2. HAZARDS IDENTIFICATION

   GHS classification of chemical product
   Reproductive toxicity : Category 1B
   Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Testis)
   Long-term (chronic) aquatic hazard : Category 3

   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.
                      H412 Harmful 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.
                            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.

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
Important symptoms and outlines of the emergency assumed:
- Dust contact with the eyes can lead to mechanical irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.
- May form explosive dust-air mixture during processing, handling or other means.

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>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
</tr>
<tr>
<td>Finasteride</td>
<td>98319-26-7</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
</tr>
<tr>
<td>Diiron trioxide</td>
<td>1309-37-1</td>
</tr>
<tr>
<td>Iron oxide</td>
<td>1332-37-2</td>
</tr>
<tr>
<td>Sodium bis(2-ethylhexyl)sulfosuccinate</td>
<td>577-11-7</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.
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:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
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 spills cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfa-
ences, as these may form an explosive mixture if they are re-
leased into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures:  Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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.
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 as-
ssessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:  Oxidizing agents

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.

Storage

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

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</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>TWA</td>
<td>10 mg/m³</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>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Titanium)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Iron oxide</td>
<td>1332-37-2</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Iron)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Iron)</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Diiron trioxide</td>
<td>1309-37-1</td>
<td>OEL-M (Respirable dust)</td>
<td>1 mg/m³ (Iron)</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Iron)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Class 2 Dust

These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

Titanium dioxide

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**: 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical state**: powder
- **Colour**: tan
- **Odour**: odourless
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Boiling point, initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
- **Flammability (liquids)**: No data available
- **Lower explosion limit and upper explosion limit / flammability limit**
- **Upper explosion limit / Upper flammability limit**: No data available
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- 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:**
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

**Titanium dioxide:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

**Diiron trioxide:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

**Iron oxide:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials
SAFETY DATA SHEET

Finasteride (1%) Formulation

Version: 10.1  Revision Date: 2020/10/10  SDS Number: 49649-00017  Date of last issue: 2020/03/23  Date of first issue: 2015/01/26

Sodium bis(2-ethylhexyl)sulfosuccinate:
Acute oral toxicity : LD50 (Rat): 3,080 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

Finasteride:
Species : Rabbit
Result : No skin irritation

Titanium dioxide:
Species : Rabbit
Result : No skin irritation

Diiron trioxide:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Iron oxide:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Sodium bis(2-ethylhexyl)sulfosuccinate:
Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

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

Components:

Starch:
Species : Rabbit
Result : No eye irritation

Finasteride:
Species : Rabbit
Remarks : slight irritation
Titanium dioxide:
Species : Rabbit
Result : No eye irritation

Diiron trioxide:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Iron oxide:
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Sodium bis(2-ethylhexyl)sulfosuccinate:
Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

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
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Titanium dioxide:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative

Diiron trioxide:
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Iron oxide:
Exposure routes : Skin contact
Species : Guinea pig
SAFETY DATA SHEET

Finasteride (1%) Formulation

Result: negative
Remarks: Based on data from similar materials

Sodium bis(2-ethylhexyl)sulfosuccinate:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Species: Humans
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

Titanium dioxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

Diiron trioxide:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Iron oxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Sodium bis(2-ethylhexyl)sulfosuccinate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: equivocal
Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Cellulose:
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

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)
SAFETY DATA SHEET
Finasteride (1%) Formulation

Result: negative
Target Organs: Testes
Remarks: Benign tumor(s)

Titanium dioxide:
Species: Rat
Application Route: Inhalation (dust/mist/fume)
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

Diiiron trioxide:
Species: Rat
Application Route: Intraperitoneal injection
Exposure time: 790 - 914 days
Result: negative

Iron oxide:
Species: Rat
Application Route: Intraperitoneal injection
Exposure time: 790 - 914 days
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
May damage the unborn child.

Components:
Cellulose:
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

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
### 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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>LOAEL: 0.003 mg/kg body weight</td>
<td>Teratogenic effects, Embryotoxic effects</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Monkey</td>
<td>Ingestion</td>
<td>LOAEL: 2 mg/kg body weight</td>
<td>Teratogenic effects</td>
</tr>
</tbody>
</table>

### Reproductive Toxicity - Assessment

- Clear evidence of adverse effects on development, based on animal experiments.

### Sodium bis(2-ethylhexyl)sulfosuccinate:

#### Effects on Fertility

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Effects on Foetal Development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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.

#### Iron oxide:

- **Exposure routes**: Inhalation (dust/mist/fume)
- **Assessment**: No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.
Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: \( \geq 9,000 \text{ mg/kg} \)
Application Route: Ingestion
Exposure time: 90 Days

Starch:
Species: Rat
NOAEL: \( \geq 2,000 \text{ mg/kg} \)
Application Route: Skin contact
Exposure time: 28 Days

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

Titanium dioxide:
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days

Species: Rat
NOAEL: 10 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 yr

Iron oxide:
Species: Rat
NOAEL: 4.7 mg/m3
Application Route: inhalation (dust/mist/fume)
Exposure time: 90 Days
Method: OECD Test Guideline 413
Remarks: Based on data from similar materials

Sodium bis(2-ethylhexyl)sulfosuccinate:
Species: Rat  
NOAEL: 750 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  

**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**  

**Components:**  

**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

**Titanium dioxide:**  
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
<table>
<thead>
<tr>
<th>Substance</th>
<th>Endpoint Description</th>
<th>EC50/EC10</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finasteride (1%) Formulation</td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td></td>
<td>Toxicity to algae/aquatic plants</td>
<td>&gt; 10,000 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td></td>
<td>Toxicity to microorganisms</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Diiron trioxide</td>
<td>Toxicity to fish</td>
<td>&gt; 50,000 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity to microorganisms</td>
<td>&gt; 10,000 mg/l</td>
<td>3 h</td>
<td></td>
</tr>
<tr>
<td>Iron oxide</td>
<td>Toxicity to fish</td>
<td>&gt; 10,000 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>&gt; 10,000 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Toxicity to microorganisms</td>
<td>&gt;= 10,000 mg/l</td>
<td>3 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>6.6 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity to algae/aquatic plants</td>
<td>82.5 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>9 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials
aquatic invertebrates (Chronic toxicity)  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms  
EC50 (Pseudomonas putida): 164 mg/l
Exposure time: 16 h

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

Sodium bis(2-ethylhexyl)sulfosuccinate:
Biodegradability  
Result: Readily biodegradable.  
Biodegradation: 91.2 %  
Exposure time: 28 d

Bioaccumulative potential

Components:

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

Sodium bis(2-ethylhexyl)sulfosuccinate:
Partition coefficient: n-octanol/water  
log Pow: 1.998  
Remarks: Calculation

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium 1,4-bis[(2-ethylhexyl)oxy]-1,4-dioxobutane-2-sulfonate</td>
<td>213</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
</table>
Titanium(IV) oxide | 191 | >=0.1 - <1
Iron oxide | 192 | >=1 - <10

Substances Subject to be Indicated Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron oxide</td>
<td>192</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste
SAFETY DATA SHEET

Finasteride (1%) Formulation

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

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

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet

Date format: yyyy/mm/dd

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

All the - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Air Transport Association; IECSC - Inventory of Existing Chemicals in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods.
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.

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