SAFETY DATA SHEET

Finasteride (3.25%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	2160722-00015	Date of first issue: 2017/11/09

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Finasteride (3.25%) Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

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.
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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	< 10
Starch	9005-25-8	< 10
Finasteride	98319-26-7	>= 2.5 -< 10

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).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL
		TWA	10 mg/m3	ACGIH
Starch	9005-25-8	NAB	10 mg/m3	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA	10 mg/m3	ACGIH
Finasteride	98319-26-7	TWA	0.5 µg/m3 (OEB 5)	Internal
		Wipe limit	5 µg/100 cm²	Internal

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 tech-

nology 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
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	:	No hazardous decomposition products are known.

products

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:

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

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

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

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

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

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 (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

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

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	:	Do not dispose of waste into sewer. 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
Environmentally hazardous	:	yes

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
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 Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2023/09/30

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
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

AIIC - 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 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 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 (Median Lethal Dose); 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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