

Finasteride (3.25%) Formulation

Version 2.5			DS Number: 60728-00009	Date of last issue: 10/10/2020 Date of first issue: 11/09/2017		
SECTION	1. IDENTIFICATION					
	uct name means of identification	:	Finasteride (3.25 No data available			
Manı	facturer or supplier's	deta	ails			
Comp Addre Telep	bany name of supplier ess hone	:	Organon & Co. 30 Hudson Stree Jersey City, New 551-430-6000	et, 33nd floor / Jersey, U.S.A 07302		
	gency telephone il address	:	215-631-6999 EHSSTEWARD	@organon.com		
Reco	mmended use of the c	hen	nical and restrict	ions on use		
Reco	mmended use	:	Pharmaceutical			
Restr	ictions on use	:	Not applicable			
Repro Spec	oductive toxicity ific target organ toxicity eated exposure (Oral)	:	Category 1B	rdous Products Regulations tis)		
GHS	label elements					
Haza	rd pictograms	:				
Signa	l Word	:	Danger			
Haza	rd Statements	:		nage the unborn child. Image to organs (Testis) through prolonged or Ire if swallowed.		
Preca	autionary Statements	:	P202 Do not har and understood. P260 Do not bre P264 Wash skin P270 Do not eat	ecial instructions before use. Indle until all safety precautions have been read athe dust, fume, gas, mist, vapors or spray. thoroughly after handling. , drink or smoke when using this product. ective gloves, protective clothing, eye protection ion.		

Response:

P308 + P313 IF exposed or concerned: Get medical attention.



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		Storag	je:	
		P405 \$	Store locked	up.
		Dispo	sal:	
			Dispose of c al plant.	ontents and container to an approved wa
Other	r hazards			
	known.			
CTION		N/INFORMATION : Mixtur		DIENTS
CTION Subst	3. COMPOSITIO			DIENTS
CTION Subst	3. COMPOSITIO		e CAS-No.	DIENTS Concentration (% w/w)
CTION Subst	3. COMPOSITIO cance / Mixture conents nical name	: Mixtur	e CAS-No.	
CTION Subst Comp Cherr	3. COMPOSITIO cance / Mixture conents nical name ose	: Mixtur Common Name/Synonym No data availa-	e CAS-No.	Concentration (% w/w)

SECTION 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 Protection of first-aiders	:	May damage the unborn child. Causes damage to organs through prolonged or repeated exposure if swallowed. First Aid responders should pay attention to self-protection,
Notes to physician	:	and use the recommended personal protective equipment when the potential for exposure exists (see section 8). Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

SAFETY DATA SHEET



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	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
	Unsuita media	able extinguishing	:	None known.	
		c hazards during fire	:	Exposure to comb	pustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides Metal oxides	
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray to	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
		protective equipment fighters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
SEC	CTION 6	. ACCIDENTAL RELE	AS	EMEASURES	
	tive equ	al precautions, protec- uipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
	Enviror	nmental precautions	:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. should be advised if significant spillages
		ls and materials for ment and cleaning up	:	container for dispo Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	tum up spillage and collect in suitable osal. regulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements.

SECTION 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, vapors 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



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		-	ightly closed. or smoke when using this product. vent spills, waste and minimize release to the				
Conditions for safe storage		 Keep in properly labeled 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 Organic peroxides Explosives Gases 					

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWÁ (respir- able dust fraction)	3 mg/m³	CA BC OEL
		TWAEV (to- tal dust)	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Starch	9005-25-8	TWA	10 mg/m³	CA AB OEL
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respir- able dust fraction)	3 mg/m ³	CA BC OEL
		TWA	10 mg/m ³	ACGIH
Finasteride	98319-26-7	TWA	0.5 µg/m3 (OEB 5)	Internal
		Wipe limit	5 µg/100 cm ²	Internal

Ingredients with workplace control parameters

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

Totally enclosed processes and materials transport systems are required.



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			equire the use of appropriate containment designed to prevent leakage of compounds into ce.
Perse	onal protective equip	ment	
	iratory protection	exposure as recommende	ocal exhaust ventilation is not available or sessment demonstrates exposures outside the ed guidelines, use respiratory protection.
	lter type I protection	: Particulates	type
M	aterial	: Chemical-re	sistant gloves
	emarks protection	If the work e mists or aero Wear a face	uble gloving. glasses with side shields or goggles. nvironment or activity involves dusty conditions, psols, wear the appropriate goggles. shield or other full face protection if there is a direct contact to the face with dusts, mists, or
Skin :	and body protection	Additional bo task being p disposable s	n or laboratory coat. ody garments should be used based upon the erformed (e.g., sleevelets, apron, gauntlets, suits) to avoid exposed skin surfaces. iate degowning techniques to remove potentially d clothing.
Hygie	ene measures	: If exposure t eye flushing working plac When using Wash contai The effective engineering appropriate industrial hys	o chemical is likely during typical use, provide systems and safety showers close to the

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Color	:	blue
Odor	:	odorless
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable



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	Evapor	ation rate	:	Not applicable			
	Flamma	ability (solid, gas)	:	Not classified as	a flammability hazard		
	Flamma	ability (liquids)	:	No data available)		
		explosion limit / Upper bility limit	:	No data available			
		explosion limit / Lower bility limit	:	No data available			
	Vapor p	oressure	:	Not applicable			
	Relative	e vapor density	:	Not applicable			
	Relative	e density	:	No data available			
	Density	/	:	No data available	9		
	Solubili Wat	ity(ies) er solubility	:	No data available	9		
		n coefficient: n-	:	Not applicable			
	octanol Autoigr	/water hition temperature	:	No data available	9		
	Decom	position temperature	:	No data available	9		
	Viscosi Visc	ty cosity, kinematic	:	Not applicable			
	Explosi	ve properties	:	Not explosive			
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.		
	Particle	e size	:	No data available			

SECTION 10. STABILITY AND REACTIVITY

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





rsion	Revision Date: 04/09/2021		S Number: 60728-00009	Date of last issue: 10/10/2020 Date of first issue: 11/09/2017
CTION	11. TOXICOLOGICA			
CHON	TT. TOXICOLOGICA			
	nation on likely rout	es of	exposure	
	contact			
Ingest Eye ce	ontact			
Acute	e toxicity			
Not cla	assified based on ava	ailable	information.	
<u>Produ</u>	<u>ict:</u>			
Acute	oral toxicity	:	Acute toxicity e Method: Calcul	estimate: > 5,000 mg/kg lation method
Comp	oonents:			
Cellul	lose:			
Acute	oral toxicity	:	LD50 (Rat): > 5	5,000 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5	5.8 mg/l
			Exposure time:	24 h
			Test atmosphe	re: dust/mist
Acute	dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg
Starc	h:			
Acute	oral toxicity	:	LD50 (Rat): > 5	5,000 mg/kg
Acute	dermal toxicity	:	LD50 (Rabbit):	> 2,000 mg/kg
Finas	teride:			
Acute	oral toxicity	:	LD50 (Rat): 37	3 - 828 mg/kg
			LD50 (Mouse):	486 mg/kg
Skin d	corrosion/irritation			
Not cl	assified based on ava	ailable	information.	
<u>Comp</u>	oonents:			
Finas	teride:			
Specie		:	Rabbit	
Resul	t	:	No skin irritatio	n
Serio	us eye damage/eye	irritati	on	
	assified based on ava			
Comp	oonents:			
Starc	h:			
Specie		:	Rabbit	
Resul		:	No eye irritatio	n



ersion 5	Revision Date: 04/09/2021		Number: 28-00009	Date of last issue: 10/10/2020 Date of first issue: 11/09/2017
	steride:	D		
Speci Rema			abbit ght irritation	
Resp	iratory or skin sens	itization		
-	sensitization lassified based on av	ailable info	ormation.	
-	iratory sensitization		ormation.	
Com	ponents:			
Starc Test Route Speci Resu	Type es of exposure ies	: Sk : Gu	aximization To in contact uinea pig gative	est
	cell mutagenicity lassified based on av	ailable info	ormation.	
<u>Com</u>	ponents:			
Cellu Geno	lose: toxicity in vitro		est Type: Bact esult: negative	terial reverse mutation assay (AMES)
			est Type: In vi esult: negative	tro mammalian cell gene mutation test
Geno	toxicity in vivo	cy Sp Ap	est Type: Man togenetic ass pecies: Mouse oplication Rou esult: negative	e ite: Ingestion
Starc	h:			
Geno	toxicity in vitro		est Type: Bact esult: negative	terial reverse mutation assay (AMES)
Finas	steride:			
Geno	toxicity in vitro		est Type: Chro esult: positive	omosome aberration test in vitro
			est Type: In vi esult: negative	tro mammalian cell gene mutation test
			Journ nogani	



ersion 5	Revision Date: 04/09/2021		S Number: 60728-00009	Date of last issue: 10/10/2020 Date of first issue: 11/09/2017
			Test Type: Alkal Result: negative	ine elution assay
Genot	oxicity in vivo	:		
	n ogenicity assified based on avail	able	information.	
Comp	onents:			
Cellul	ose:			
	ation Route sure time	:	Rat Ingestion 72 weeks negative	
Finas	teride:			
	es ation Route sure time	:	Rat Ingestion 2 Years	uusiaht
Resul Targe Rema	t Organs	:	160 mg/kg body negative Testes Benign tumor(s)	
Expos Resul	ation Route sure time t t Organs		Mouse Ingestion 19 month(s) negative Testes Benign tumor(s)	
Repro	oductive toxicity			
•	amage the unborn child	d.		
Comp	onents:			
Cellul	ose:			
Effects	s on fertility	:	Test Type: One- Species: Rat Application Rour Result: negative	
Effect	s on fetal development	:	Test Type: Ferti Species: Rat Application Rou Result: negative	
Finas	teride:			
	s on fertility	:	Test Type: Ferti	lity/early embryonic development



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			Species: Rat Application Ro Fertility: LOAE Result: positiv	se is no evidence that these findings are rele-
	Effects on fetal development		Species: Rat Application Ro Developmenta	nbryo-fetal development oute: Ingestion al Toxicity: LOAEL: 0.003 mg/kg body weight ogenic effects., Embryotoxic effects.
			Species: Mon Application Re	oute: Ingestion al Toxicity: LOAEL: 2 mg/kg body weight
	Reprod sessme	luctive toxicity - As- ent	: Clear evidenc animal experi	e of adverse effects on development, based on ments.
		single exposure ssified based on availa	ble information.	
	STOT-I	repeated exposure		

Causes damage to organs (Testis) through prolonged or repeated exposure if swallowed.

Components:

Assessment

Finasteride:Routes of exposure:Target Organs:Testis

	5
:	Testis
:	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



Toxicity to daphnia and other :

aquatic invertebrates

plants

Toxicity to algae/aquatic

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App Exp	NOAEL Application Route Exposure time Method		00 mg/kg intact s Test Guide	eline 410		
Fina	asteride:					
Exp	\EL	: Rat : 20 mg/l : 40 mg/l : Oral : 1 y : Testis				
Exp		: Dog : 45 mg/l : Oral : 1 y : Testis	kg			
Not	Aspiration toxicity Not classified based on available information. Experience with human exposure					
<u>Con</u>	nponents:					
	asteride: estion			t tenderness, breast enlargement, impo- , skin rash		
SECTIO	N 12. ECOLOGICAL INI	ORMATION				
Eco	toxicity					
<u>Con</u>	nponents:					
	ulose: city to fish	Exposu	ire time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials		
Fina	asteride:					
Тохі	city to fish	Exposu	Oncorhync ire time: 96 I: FDA 4.17			

Exposure time: 48 h Method: FDA 4.08

Exposure time: 14 h

:

mg/l

EC50 (Daphnia magna (Water flea)): 17.8 mg/l

NOEC (Pseudokirchneriella subcapitata (green algae)): 49



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			Method: FDA 4.0	1
Toxic icity)	to fish (Chronic tox-	:	NOEC (Oryzias la Exposure time: 10	tipes (Orange-red killifish)): 0.05 mg/l 05 d
aqua	Toxicity to daphnia and other aquatic invertebrates (Chron-ic toxicity)		NOEC (Daphnia magna (Water flea)): 0.12 mg/l Exposure time: 21 d Method: OECD Test Guideline 211	
Pers	istence and degradabili	ity		
<u>Com</u>	ponents:			
Cellu	llose:			
Biode	egradability	:	Result: Readily bi	odegradable.
Finas	steride:			
Biode	egradability	:	Result: Not readil Biodegradation: Exposure time: 7 Method: FDA 3.1) % d
Stabi	lity in water	:	Hydrolysis: 0 %(5 Method: FDA 3.09	
Bioa	ccumulative potential			
<u>Com</u>	ponents:			
Finas	steride:			
	tion coefficient: n- nol/water	:	log Pow: 3.57	
Mobi	ility in soil			
No da	ata available			
	r adverse effects			
No da	ata available			

SECTION 13. DISPOSAL CONSIDERATIONS

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

International Regulations

UNRTDG

UN	number
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: UN 3077



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	Proper shipping name		:	ENVIRONMENTA N.O.S. (Finasteride)	ALLY HAZARDOUS SUBSTANCE, SOLID,
	Class		:	9	
	Packing	g group	:	III	
	Labels		:	9	
	IATA-E Un/ID	No.	:	UN 3077	
		shipping name	:	(Finasteride)	nazardous substance, solid, n.o.s.
	Class		:	9	
		g group	:	 Minan llaw a sure	
	Labels Packing aircraft	g instruction (cargo	:	Miscellaneous 956	
		g instruction (passen-	:	956	
	Enviror	nmentally hazardous	:	yes	
	IMDG-	Code			
	UN nur	mber	:	UN 3077	
	Proper	shipping name	:	ENVIRONMENTA N.O.S. (Finasteride)	ALLY HAZARDOUS SUBSTANCE, SOLID,
	Class		:	9	
		g group	:	III	
	Labels		:	9	
	EmS C		:	F-A, S-F	
	Marine	pollutant	:	yes	
	Transp	oort in bulk according	g to	Annex II of MARP	OL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

TDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
		(Finasteride)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Finasteride)

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.

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined



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DSL		: not determined		
IECSC		: not determined		

SECTION 16. OTHER INFORMATION

Full text of other abbreviations				
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)		
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)		
CA BC OEL	:	Canada. British Columbia OEL		
CA QC OEL	:	Québec. Regulation respecting occupational health and safe- ty, Schedule 1, Part 1: Permissible exposure values for air- borne contaminants		
ACGIH / TWA	:	8-hour, time-weighted average		
CA AB OEL / TWA	:	8-hour Occupational exposure limit		
CA BC OEL / TWA	:	8-hour time weighted average		
CA QC OEL / TWAEV	:	Time-weighted average exposure value		

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; 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

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD



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compile the Material Safety		eChem Portal search results and European Chemicals Agen-		
Data Sheet		cy, http://echa.europa.eu/		
Revision Date Date format		: 04/09/2021 : mm/dd/yyyy		

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.

CA / Z8