

Finasteride (1%) Formulation

Vers 6.8	sion	Revision Date: 2021/04/09	-	S Number: 43-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26		
1. P	RODUC	T AND COMPANY IDE	ENT	FICATION			
	Product	name	:	Finasteride (1%)	Formulation		
	Manufa	cturer or supplier's d	etai	ls			
	Compa	ny	:	Organon & Co.			
	Address	5	:	JL Raya Pandaan KM. 48 Pandaan, Jawa Timur - Indonesia			
	Telepho	one	:	551-430-6000			
	Emerge	ency telephone number	:	215-631-6999			
	E-mail a	address	:	EHSSTEWARD@organon.com			
	Recom	mended use of the ch	nemi	ical and restrictio	ons on use		
	Recom	mended use	:	Pharmaceutical			
2. H	AZARD	S IDENTIFICATION					
	GHS CI	assification					
	Reprod	uctive toxicity	:	Category 1B			
		target organ toxicity - d exposure (Oral)	:	Category 2 (Test	is)		
	Long-te hazard	rm (chronic) aquatic	:	Category 3			

GHS label elements

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.



Version 6.8	Revision Date: 2021/04/09	SDS Number: 49643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/
		Storage: P405 Store lo	cked up.
		Disposal:	

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

Other hazards which do not result in classification

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

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	>= 1 -< 2.5
Titanium dioxide	13463-67-7	< 1

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice 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	:	If in eyes, rinse well with water. 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. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.



Version 6.8	Revision Date: 2021/04/09		0S Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
	ction of first-aiders to physician	:	and use the recon when the potentia	ers should pay attention to self-protection, nmended personal protective equipment I for exposure exists (see section 8). cally and supportively.
5. FIREFIC	GHTING MEASURES			
Suitab	ble extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
Unsui media	table extinguishing	:	None known.	
	fic hazards during fire-	:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. oustion products may be a hazard to health.
Hazar ucts	dous combustion prod-	:	Carbon oxides Metal oxides	
Speci ods	fic extinguishing meth-	:	cumstances and t Use water spray t	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
	al protective equipment efighters	:		e, wear self-contained breathing apparatus. ective equipment.
6. ACCIDE	ENTAL RELEASE MEAS	SUF	RES	
tive e	nal precautions, protec- quipment and emer- procedures	:		ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8).
Enviro	onmental precautions	:	Retain and dispos	akage or spillage if safe to do so. e of contaminated wash water. should be advised if significant spillages
	ods and materials for inment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces



Finasteride (1%) Formulation

Version 6.8	Revision Date: 2021/04/09	SDS Number: 49643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
7. HAND	LING AND STORAGE		
	nnical measures	causing an expl Provide adequa and bonding, or	te precautions, such as electrical grounding inert atmospheres.
Loca	al/Total ventilation	: If sufficient vent ventilation.	ilation is unavailable, use with local exhaust
Advi	ce on safe handling	 Do not get on sl Do not breathe Do not swallow. Avoid contact w Wash skin thoro Handle in accor practice, based sessment Keep container Minimize dust g Keep container Keep away from Take precaution Do not eat, drinl 	dust. ith eyes. bughly after handling. dance with good industrial hygiene and safety on the results of the workplace exposure as-
	ditions for safe storage	: Keep in properly Store locked up Keep tightly clos Store in accords	sed. ance with the particular national regulations.
Mate	erials to avoid	: Do not store wit Strong oxidizing	h the following product types: agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
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 inform	nation: Not class	sified as carcinogenic	to humans. Not	
	enough data t	enough data to classify these materials as carcinogenic to			
	mans or anim	als			
		TWA	10 mg/m3	ACGIH	
Finasteride	98319-26-7	TWA	0.5 µg/m3 (OEB	Internal	
			5)		
		Wipe limit	5 µg/100 cm ²	Internal	
Titanium dioxide	13463-67-7	NAB	10 mg/m3	ID OEL	
	Further inform	nation: Not class	sified as carcinogenic	to humans. Not	
	enough data t	o classify these	materials as carcinog	genic to hu-	
	mans or anim	als			

Components with workplace control parameters



			TWA	10 mg/m3	ACGIH
	e substance(s) are in dust inhalation hazaro Titanium dioxi	ł.	nd in the product a	(Titanium dioxide)	
Engii	neering measures	to control vent leaka All engine design an protect pr No open Totally en are requin Operation	at source (e.g., glo age of compounds eering controls sho ad operated in acco oducts, workers, a handling permitted iclosed processes red. as require the use of esigned to prevent	ems or containment to bye boxes/isolators) a into the workplace. uld be implemented b ordance with GMP pri nd the environment. and materials transpo of appropriate contair leakage of compound	and to pre- by facility nciples to prt systems ament tech-
Perso	onal protective equip	ment			
Fil	iratory protection Iter type protection	sure asse	essment demonstrated guidelines, use i	ntilation is not availal ates exposures outsic respiratory protection	le the rec-
M	aterial	: Chemical	-resistant gloves		
			-		
	emarks protection	: Wear safe If the wor mists or a Wear a fa	k environment or a lerosols, wear the a leeshield or other f	de shields or goggles ctivity involves dusty appropriate goggles. ull face protection if the the face with dusts,	conditions, here is a
Skin a	and body protection	Additiona task being posable s Use appro	g performed (e.g., s uits) to avoid expo	nould be used based sleevelets, apron, ga	untlets, dis-
Hygie	ene measures	: If exposure eye flushi ing place. When usi Wash cor The effec engineeri appropria industrial	re to chemical is lik ng systems and sa ng do not eat, drinl ntaminated clothing tive operation of a ng controls, proper te degowning and	before re-use. facility should include personal protective decontamination pro g, medical surveillance	e review of equipment, cedures,

9. PHYSICAL AND CHEMICAL PROPERTIES



Ver 6.8	sion	Revision Date: 2021/04/09		S Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
	Appear	ance	:	powder	
	Colour		:	tan	
	Odour		:	odourless	
	Odour ⁻	Threshold	:	No data available	2
	рН		:	No data available	9
	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	9
	Flash p	oint	:	Not applicable	
	Evapor	ation rate	:	Not applicable	
	Flamma	ability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower bility limit	:	No data available	9
	Vapour	pressure	:	Not applicable	
	Relative	e vapour density	:	Not applicable	
	Relative	e density	:	No data available	9
	Density	,	:	No data available	9
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partitio octanol	n coefficient: n- /water	:	log Pow: 3.5 pH: 7 Active ingredient	
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty :osity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	



Vers 6.8	ion Revision Date: 2021/04/09		0S Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26				
	Oxidizing properties	:	The substance of	or mixture is not classified as oxidizing.				
	Particle size	:	: No data available					
10. S	STABILITY AND REACTIVIT	Y						
	Reactivity Chemical stability Possibility of hazardous reac- tions	:	Stable under not May form explose dling or other me	ive dust-air mixture during processing, han-				
	Conditions to avoid	:	Heat, flames and Avoid dust forma					
	Incompatible materials Hazardous decomposition products	:	Oxidizing agents					
11. T	OXICOLOGICAL INFORMA	τιοι	N					
	Information on likely routes of exposure	f:	Inhalation Skin contact Ingestion Eye contact					
	Acute toxicity Not classified based on availa	able	information.					
	Product:							
	Acute oral toxicity	:	Acute toxicity est Method: Calculat	imate: > 2,000 mg/kg ion method				
	Components:							
	Cellulose:							
	Acute oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg				
	Acute inhalation toxicity	:	LC50 (Rat): > 5.8 Exposure time: 4 Test atmosphere	h				
	Acute dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg				
	Starch:							
	Acute oral toxicity	:	LD50 (Rat): > 5,0	000 mg/kg				
	Acute dermal toxicity	:	LD50 (Rabbit): >	2,000 mg/kg				
	Finasteride:							
	Acute oral toxicity	:	LD50 (Rat): 373	- 828 mg/kg				
			LD50 (Mouse): 4	86 mg/kg				



ersion 3	Revision Date: 2021/04/09		S Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26			
Titan	ium dioxide:						
Acute	e oral toxicity	:	LD50 (Rat): >	5,000 mg/kg			
Acute	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 inhala- tion toxicity				
Skin	corrosion/irritation						
Not c	lassified based on ava	ailable	information.				
<u>Com</u>	ponents:						
Finas	steride:						
Speci Resu		:	Rabbit No skin irritatio	nc			
rtoou							
	ium dioxide:						
Speci Resu		:	Rabbit No skin irritatio	n			
<u>Com</u> Starc Speci		:	Rabbit				
Resu		:	No eye irritatio	on			
Finas	steride:						
Spec		:	Rabbit				
Rema	arks	:	slight irritation				
Titan	ium dioxide:						
Speci Resu		:	Rabbit				
Resu	IL	•	No eye irritatio	ות			
Resp	iratory or skin sensi	tisatio	n				
	sensitisation lassified based on ava	ailable	information.				
	iratory sensitisation lassified based on ava		information.				
<u>Com</u>	ponents:						
Starc	h:						
Test Expo	Type sure routes	:	Maximisation Skin contact	Test			



Species Result: Guinea pig negativeTitanium dioxide: Exposure routes Species Result: Local lymph node assay (LLNA) Exposure routes Species ResultCerm cell mutagenicity Not classified based on available information.:Cerm cell mutagenicity Result: negative:Cerm cell mutagenicity Not classified based on available information.:Cerm cell mutagenicity Result: negative:Cerm cell mutagenicity Certification route Result: negative:Cerm cell mutagenicity in vitro::Cenotoxicity in vitro::Certification Route: Ingestion Result: negative:Starch: Genotoxicity in vitro::Cenotoxicity in vitro::Cenotoxicity in vitro::Test Type: In vitro mammalian cell gene mutation test Result: negativeCenotoxicity in vitro::Cenotoxicity in vitro::Cenotoxicity in vitro::Cenotoxicity in vitro::Cenotoxicity in vitro::Cenotoxicity in vitro::Cenotoxicity	Version 6.8	Revision Date: 2021/04/09	SDS Number: 49643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
Test Type : Local lymph node assay (LLNA) Exposure routes : Skin contact Species : Mouse 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 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: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Bacterial reverse mutation assay (AMES) 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)				
Not classified based on available information. Components: Cellulose: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vitro : 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: negative Finasteride: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Alkaline elution assay (AMES) 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)	Test Type Exposure routes Species		: Skin contact : Mouse	node assay (LLNA)
Cellulose: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vivo : Test Type: 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: negative Finasteride: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Bacterial reverse mutation assay (AMES) 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)			ailable information.	
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Genotoxicity in vivo : 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: negative Finasteride: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative : Test Type: In vitro mammalian cell gene mutation test Result: negative : Test Type: Norto mammalian cell gene mutation test Result: negative : Test Type: Aklaine elution assay (AMES) : Genotoxicity in vivo : : Genotoxicity in vivo : : Genotoxicity in vivo : : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Application Route: Oral Result: negative Titanium dioxide: Genotoxi	<u>Com</u>	ponents:		
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: negative Finasteride: : Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative : Test Type: Bacterial reverse mutation assay (AMES) Result: negative : Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Application Route: Oral Result: negative Titanium dioxide: : Test Type: Bacterial reverse mutation assay (AMES)	Cellu	llose:		
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 Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Bacterial reverse mutation assay (AMES) 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)	Geno	otoxicity in vitro		
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: Racterial reverse mutation assay (AMES) 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 Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)				
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: Bacterial reverse mutation assay (AMES) Result: negative : Genotoxicity in vivo : : Genotoxicity in vivo : : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Application Route: Oral Result: negative : Titanium dioxide: : : Test Type: Bacterial reverse mutation assay (AMES) Genotoxicity in vitro : : :	Geno	otoxicity in vivo	cytogenetic a Species: Mou Application R	ssay) ise oute: Ingestion
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: 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)	Star	ch:		
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 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)	Geno	otoxicity 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)	Fina	steride:		
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)	Geno	otoxicity in vitro		
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)				
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)				
cytogenetic test, chromosomal analysis) Application Route: Oral Result: negative Titanium dioxide: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)				
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)	Geno	otoxicity in vivo	cytogenetic te Application R	est, chromosomal analysis) oute: Oral
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)	Titar	ium dioxide:		



Version 6.8	Revision Date: 2021/04/09		OS Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26		
Geno	toxicity in vivo	:	Test Type: In vivo micronucleus test Species: Mouse Result: negative			
	nogenicity					
	assified based on availa	able	information.			
Comp	oonents:					
Cellu	lose:					
	cation Route sure time	: : :	Rat Ingestion 72 weeks negative			
Finas	teride:					
Speci Applic		: : : :	Rat Ingestion 2 Years 160 mg/kg body v	voight		
Resul Targe Rema	et Organs	:	negative Testes Benign tumor(s)	veignt		
Expos Resul	cation Route sure time It et Organs	:	Mouse Ingestion 19 month(s) negative Testes Benign tumor(s)			
Titani	ium dioxide:					
Speci Applic	es cation Route sure time od It	:	Rat inhalation (dust/m 2 Years OECD Test Guide positive The mechanism of mans.			
Carcir ment	nogenicity - Assess-	:	Limited evidence animals.	of carcinogenicity in inhalation studies with		
_	oductive toxicity damage the unborn child	I.				
Comp	oonents:					
Cellu	lose:					
Effect	s on fertility	:	Test Type: One-g Species: Rat Application Route	eneration reproduction toxicity study : Ingestion		



Version 6.8	Revision Date: 2021/04/09		lumber: -00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26	
		Re	sult: negative		
	Effects on foetal develop- ment		Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative		
Fina	asteride:				
Effe	cts on fertility	Sp Ap Fe	ecies: Rabbit plication Route	80 mg/kg body weight	
		Sp Ap Fe Re	ecies: Rat plication Route rtility: LOAEL: sult: positive	y/early embryonic development e: Ingestion 80 mg/kg body weight s no evidence that these findings are rele-	
Effe men	cts on foetal develop- it	Sp Ap De	ecies: Rat plication Route velopmental T	vo-foetal development e: Ingestion oxicity: LOAEL: 0.003 mg/kg body weight nic effects, Embryotoxic effects.	
		Sp Ap De	ecies: Monkey plication Route	e: Ingestion oxicity: LOAEL: 2 mg/kg body weight	
•	roductive toxicity - As- sment		ear evidence of imal experimer	adverse effects on development, based on nts.	

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.



sion	Revision Date: 2021/04/09	SDS Numb 49643-000	
Repea	ated dose toxicity		
Comp	oonents:		
Cellul	ose:		
Speci		: Rat	
NOAE			00 mg/kg
	ation Route	: Ingestion : 90 Day	
Starc			
Speci NOAE		: Rat	00 mg/kg
	ation Route	: Skin co	
	sure time	: 28 Day	
Metho		: OECD	Test Guideline 410
Finas	teride:		
Speci	es	: Rat	
NOAE		: 20 mg/l	
LOAE		: 40 mg/l	<g< td=""></g<>
	ation Route	: Oral : 1 yr	
	t Organs	: Testis	
Speci	es	: Dog	
NOAE		: 45 mg/l	κg
	ation Route	: Oral	
	sure time t Organs	: 1 yr : Testis	
raige	Ulgans	. 16303	
	um dioxide:		
Speci		: Rat	
NOAE	:L ation Route	: 24,000 : Ingestic	
	sure time	: 28 Day	
Speci	es	: Rat	
NOAE	EL	: 10 mg/i	
	ation Route		on (dust/mist/fume)
Expos	sure time	: 2 yr	
Aspir	ation toxicity		
Not cl	assified based on ava	ilable informat	ion.
Expe	rience with human e	cposure	
<u>Comp</u>	oonents:		
	teride:		
Ingest	tion		ms: breast tenderness, breast enlargement, impo-
		tence, l	ip swelling, skin rash



Version 6.8	Revision Date: 2021/04/09		0S Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
12. ECO	LOGICAL INFORMATION	1		
Eco	otoxicity			
<u>Cor</u>	nponents:			
Cel	lulose:			
Тох	icity to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials
Fina	asteride:			
Тох	icity to fish	:	LC50 (Oncorhync Exposure time: 96 Method: FDA 4.17	
	icity to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: FDA 4.08	
Tox plar	icity to algae/aquatic nts	:	NOEC (Pseudokin mg/l Exposure time: 14 Method: FDA 4.07	
Tox icity	icity to fish (Chronic tox-	:	NOEC (Oryzias la Exposure time: 10	tipes (Orange-red killifish)): 0.05 mg/l)5 d
aqu	icity to daphnia and other atic invertebrates (Chron- pxicity)	:	NOEC (Daphnia r Exposure time: 21 Method: OECD Te	
	actor (Chronic aquatic city)	:	1	
Tita	nium dioxide:			
Тох	icity to fish	:	LC50 (Oncorhync Exposure time: 96 Method: OECD To	
	icity to daphnia and other atic invertebrates	:	EC50 (Daphnia m Exposure time: 48	agna (Water flea)): > 100 mg/l 3 h
Tox plar	icity to algae/aquatic hts	:	EC50 (Skeletoner Exposure time: 72	na costatum (marine diatom)): > 10,000 mg/ 2 h
Тох	icity to microorganisms	:	EC50: > 1,000 mg Exposure time: 3 Method: OECD Te	h



Finasteride (1%) Formulation

Vers 6.8	sion	Revision Date: 2021/04/09		OS Number: 643-00018	Date of last issue: 2020/10/10 Date of first issue: 2015/01/26
	Persis	tence and degradabi	ity		
	Comp	onents:			
	Cellulo	ose:			
	Biodeg	radability	:	Result: Readily bi	odegradable.
	Finast	eride:			
	Biodeg	radability	:	Result: Not readil Biodegradation: Exposure time: 7 Method: FDA 3.1	0 % d
	Stabilit	y in water	:	Hydrolysis: 0 %(5 Method: FDA 3.09	
	Bioaco	cumulative potential			
	Comp	onents:			
	Finast	eride:			
	Partitio octano	n coefficient: n- I/water	:	log Pow: 3.57	
	Mobili	ty in soil			
	No dat	a available			
		adverse effects			
	No dat	a available			
13. DISPOSAL CONSIDERATIONS					
	Dispos	sal methods			
	•	from residues	:	Dispose of in acc	ordance with local regulations.
		ninated packaging	:	Empty containers dling site for recy	should be taken to an approved waste han-

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.





Version	Revision Date:	SDS Number:	Date of last issue: 2020/10/10
6.8	2021/04/09	49643-00018	Date of first issue: 2015/01/26

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 substance	es that must be registered	:	Not applicable
		•	i tot upplioublo

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, : Diiron trioxide Distribution and Supervision

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	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/
Date format	:	yyyy/mm/dd
Full text of other abbreviatio	ons	
ACGIH ID OEL	:	USA. ACGIH Threshold Limit Values (TLV) Indonesia. Occupational Exposure Limits
ACGIH / TWA ID OEL / NAB	:	8-hour, time-weighted average Long term exposure limit



Finasteride (1%) Formulation

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6.8	2021/04/09	49643-00018	Date of first issue: 2015/01/26

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

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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