

DUTASTERIDE

Dr.Reddy's Laboratories

Chemwatch: 3865456

Version No: 2.1.1.1

Safety Data Sheet

Chemwatch Hazard Alert Code: 2

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Initial Date: Not Available

L.GHS.IND.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

Product name	DUTASTERIDE
Chemical Name	dutasteride
Synonyms	(4aR,4bS,6aS,7S,9aS,9bS,11aR)-N-[2,5-bis(trifluoromethyl)phenyl]-2,4a,4b,5,6,6a,7,8,9,9a,9b,10,11,11a-tetradecahydro-4a,6a-dimethyl-2-oxo-1H-indeno[5,4-f]quinoline-7-carboxamide, (5 alpha 17 beta)N{2 5 bis(trifluoromethyl)phenyl}, (5alpha, 17beta)-N-{2,5 bis(trifluoromethyl) phenyl}-3-oxo-4-azaandrost-1-ene-17-carboxamide, 17beta-N-[2,5-bis(trifluoromethyl)phenyl]carbamoyl-4-aza-5a-androst-1-en-3-one, 5alpha-0reductase inhibitor, Avodart, Avolve, C27-H30-F6-N2-O2, Dutasteride, GG-756, GI-198745, antiprostatic hypertrophy drug
Chemical formula	C27H30F6N2O2
Other means of identification	Not Available
CAS number	164656-23-9

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	For treatment of benign prostatic hyperplasia (BPH) and prescribed off-label for treatment of male pattern baldness (MPB).. A dual 5-alpha reductase inhibitor that inhibits conversion of testosterone to dihydrotestosterone (DHT). Analogue of finasteride.
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Details of the supplier of the safety data sheet

Registered company name	Dr.Reddy's Laboratories
Address	7-1-27/1 India
Telephone	04049002900
Fax	Not Available
Website	IND
Email	Not Available

Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture


CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	1	2
Toxicity	2	3
Body Contact	2	3
Reactivity	1	2
Chronic	2	3

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

GHS Classification	Carcinogen Category 2, Reproductive Toxicity Category 2
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Label elements

GHS label elements	
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SIGNAL WORD	WARNING
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Hazard statement(s)

Continued...

H351	Suspected of causing cancer
H361	Suspected of damaging fertility or the unborn child

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
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Precautionary statement(s) Storage

P405	Store locked up.
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Precautionary statement(s) Disposal

P501	Dispose of contents/container in accordance with local regulations.
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SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS**Substances**

CAS No	%[weight]	Name	GHS Classification
Not Available	>98	dutasteride	Not Applicable

Mixtures

See section above for composition of Substances

SECTION 4 FIRST AID MEASURES**Description of first aid measures**

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If dust is inhaled, remove from contaminated area. ▶ Encourage patient to blow nose to ensure clear passage of breathing. ▶ If irritation or discomfort persists seek medical attention.
Ingestion	<ul style="list-style-type: none"> ▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Seek medical advice.

Indication of any immediate medical attention and special treatment needed

DUTASTERIDE

Treat symptomatically.

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

BASIC TREATMENT

- ▶ Establish a patent airway with suction where necessary.
- ▶ Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- ▶ Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- ▶ Monitor and treat, where necessary, for pulmonary oedema.
- ▶ Monitor and treat, where necessary, for shock.
- ▶ Anticipate seizures.
- ▶ **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

ADVANCED TREATMENT

- ▶ Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- ▶ Monitor and treat, where necessary, for arrhythmias.
- ▶ Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- ▶ Drug therapy should be considered for pulmonary oedema.
- ▶ Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- ▶ Treat seizures with diazepam.
- ▶ Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). ▶ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. <p>Combustion products include; carbon monoxide (CO) carbon dioxide (CO₂) hydrogen fluoride, nitrogen oxides (NO_x) other pyrolysis products typical of burning organic material May emit poisonous fumes.</p>

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust.
Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> ▶ CAUTION: Advise personnel in area. ▶ Alert Emergency Services and tell them location and nature of hazard. ▶ Control personal contact by wearing protective clothing.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) ▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ▶ Establish good housekeeping practices.
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DUTASTERIDE

	<ul style="list-style-type: none"> Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Other information	<ul style="list-style-type: none"> Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> Glass container is suitable for laboratory quantities Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> Avoid reaction with oxidising agents

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
DUTASTERIDE	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
dutasteride	Not Available	Not Available

MATERIAL DATA

For finasteride:

CEL TWA: 0.005 mg/m³ [Manufacturer]


(CEL = Chemwatch Exposure Limit)

Wipe-Test Criteria: 0.0005 ug/100 cm²

The no-effect level for lowering serum dihydrotestosterone (DHT) in clinical trials with males was determined to be 5 ug/day. Therefore in the course of a work-day, an individual breathing 10 m³ of air will exceed this limit if air concentrations exceed 0.5 ug/m³ (assuming respiratory intake is equivalent to oral intake). Exposure by both male and female workers at or below the recommended level is thought to provide an adequate margin of safety against diminished prostate size in males and to protect the foetus from congenital malformation. The wipe test criteria assumes 100 % of the material can be absorbed directly through the skin (and by ingestion).

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

Exposure controls

Appropriate engineering controls	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.</p> <p>HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.</p> <p>Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.</p> <p>A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p>
Personal protection	
Eye and face protection	<p>When handling very small quantities of the material eye protection may not be required.</p> <p>For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> Chemical goggles. Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
Skin protection	See Hand protection below
Hands/feet protection	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Suitability and durability of glove type is dependent on usage.</p> <ul style="list-style-type: none"> Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. Double gloving should be considered. PVC gloves. <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> polychloroprene. nitrile rubber. butyl rubber.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
Thermal hazards	Not Available

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DUTASTERIDE

Respiratory protection

Not Available

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	White crystalline solid; does not mix well with water.		
Physical state	Divided Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Applicable	Decomposition temperature	Not Available
Melting point / freezing point (°C)	245	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	528.53
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Negligible
Vapour pressure (kPa)	Negligible	Gas group	Not Available
Solubility in water (g/L)	Partly Miscible	pH as a solution (1%)	Not Applicable
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	<p>The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.</p> <p>Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p>
Ingestion	<p>Impotence, decreased libido or decreased volume of ejaculate are the most commonly reported adverse effects of finasteride treatment. Other effects include enlargement of the breasts and breast tenderness in males, and hypersensitivity reactions including lip-swelling and skin rash. A no-effect level in clinical trials was 5 ug/day (multiple dose, 21 days).</p>

Continued...

DUTASTERIDE

	When given to dogs and rats at doses up to 80 mg/kg/day, for 14 weeks, reduced prostate gland weights were noted. Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.				
Skin Contact	The material is not thought to be a skin irritant (as classified by EC Directives using animal models). Abrasive damage however, may result from prolonged exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Skin contact with the material may damage the health of the individual; systemic effects may result following absorption. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.				
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.				
Chronic	On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment. Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, generally on the basis that results in appropriate animal studies provide strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects. The patient's sexual partner may become exposed to finasteride through the semen (small amounts have been recovered in the semen of patients receiving 5 mg/day). The material should not be handled by women who are or may become pregnant because of the possibility of absorption. Animal studies show feminisation of the male foetus. In patients receiving treatment with finasteride, for 1 year, an increase in luteinising hormone (by 15%) and follicle-stimulating hormone (by 9%) has been described. 5 alpha-Reductase inhibitors may cause abnormalities of the external genitalia of a male foetus. Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.				
DUTASTERIDE	<table> <tr> <th>TOXICITY</th><th>IRRITATION</th></tr> <tr> <td>Not Available</td><td>Not Available</td></tr> </table>	TOXICITY	IRRITATION	Not Available	Not Available
TOXICITY	IRRITATION				
Not Available	Not Available				
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances				

DUTASTERIDE	No significant acute toxicological data identified in literature search. Causes birth defects in male embryos and fetuses, but not in female. Dutasteride has teratogenic effects in male fetuses. It causes abnormalities of physiological development if during gestation a pregnant woman is exposed to dutasteride. Women who are pregnant should not handle the capsules since dutasteride is absorbed through the skin. The adverse effects of dusteride are identical to 5-alpha-reductase deficiency, where a developing male child is naturally deficient in 5-alpha reductase type II, and thus unable to synthesise it. As dutasteride inactivates 5-alpha reductase type II developing males would have the same adverse effects as a result of the drug as they would have with the deficiency. The FDA has added warning to dutasteride about an increased risk of high-grade prostate cancer. While the potential for positive, negative or neutral changes to the potential risk of developing prostate cancer with dutasteride has not been established, evidence has suggested it may temporarily reduce the growth and prevalence of benign prostate tumors, but could also mask the early detection of prostate cancer. The primary area for concern is for patients who may develop prostate cancer whilst taking dutasteride for benign prostatic hyperplasia, which in turn could delay diagnosis and early treatment of the prostate cancer, thereby potentially increasing the risk of these patients developing high-grade prostate cancer
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Acute Toxicity	☐	Carcinogenicity	✓
Skin Irritation/Corrosion	☐	Reproductivity	✓
Serious Eye Damage/Irritation	☐	STOT - Single Exposure	☐
Respiratory or Skin sensitisation	☐	STOT - Repeated Exposure	☐
Mutagenicity	☐	Aspiration Hazard	☐

Legend: ✗ – Data available but does not fill the criteria for classification
 ✓ – Data required to make classification available
 ☐ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

For finasteride:

Kow : 3.17E+03

Environmental fate:

Finasteride appears to be resistant to biological oxidation by an acclimated mixed microbial population of activated sludge origin.

Finasteride does not appear to be photosensitive

Ecotoxicity:

Fish LC50 (96h) 14-22 mg/l

Fish LC50 (96 h): rainbow trout 19.6 mg/l (slightly toxic)

Daphnia magna LC50 (48 h): 21 mg/l (slightly toxic)

In a chronic toxicity study of finasteride to green alga (Selenastrum capricornutum), it was determined that the no-observed-effect-level after a 14-day incubation period is equal or greater than 49 mg/l.

This level is the approximate solubility limit of finasteride in water.

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DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible.
	<p>Otherwise:</p> <ul style="list-style-type: none"> If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> Reduction Reuse Recycling Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none"> DO NOT allow wash water from cleaning or process equipment to enter drains. It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. Recycle wherever possible. Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material) Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
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Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

SECTION 15 REGULATORY INFORMATION

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

National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	Y
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y

Legend:*Y = All ingredients are on the inventory**N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)***SECTION 16 OTHER INFORMATION****Other information**

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net

The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC — TWA: Permissible Concentration-Time Weighted Average

PC — STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

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TEL (+61 3) 9572 4700.