

1. Identification

Product identifier	Dutasteride
Other means of identification	
Catalog number	1229922
CAS number	164656-23-9
Chemical name	(5 α ,17 β)-N-(2,5-Bis(trifluoromethyl)phenyl)-3-oxo-4-azaandrost-1-ene-17-carboxamide
Recommended use	Specified quality tests and assay use only.
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company name	U. S. Pharmacopeia
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States
Telephone	RS Technical Services 301-816-8129
Website	www.usp.org
E-mail	RSTECH@usp.org
Emergency phone number	CHEMTREC within US & 1-800-424-9300 Canada CHEMTREC outside US & +1 703-527-3887 Canada

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 1B
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Danger
Hazard statement	May damage fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Potent pharmacologically active material.

3. Composition/information on ingredients

Substance			
Chemical name	Common name and synonyms	CAS number	%
Dutasteride		164656-23-9	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
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Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Reproductive system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

Exposure limit values

Industrial Use Material

Type

Value

Dutasteride (CAS
164656-23-9)

TWA

0.3 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White. Pale yellow.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	467.6 - 482 °F (242 - 250 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Insoluble.
Solubility (other)	Ethanol: Soluble. Chloroform: Soluble. Tetrahydrofuran: Soluble. Dimethyl Sulfoxide: Soluble. Methanol: Soluble.
Partition coefficient (n-octanol/water)	3.87 (pH 6)
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	4-Azasteroid.
Molecular formula	C27H30F6N2O2

Molecular weight 528.54

10. Stability and reactivity

Reactivity	None known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	None known.
Hazardous decomposition products	F-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	In males: Impotence. Decreased ejaculate. Decreased sexual desire. Swelling or tenderness of breasts. Skin rash.

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Dutasteride (CAS 164656-23-9)		
Oral	Rat	> 2000 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Based on available data, the classification criteria are not met.

Buehler test
Result: Negative
Species: Guinea pig

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test
Result: Negative.
Chromosome aberration, Chinese hamster ovary cells
Result: Negative.
Micronucleus test
Result: Negative.
Species: Rat
Mutagenicity, L5178Y mouse lymphoma thymidine kinase locus assay
Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity May damage fertility or the unborn child.
5 alpha-reductase inhibitors prevent conversion of testosterone to dihydrotestosterone (DHT), a hormone necessary for normal development of male genitalia. In animal reproduction and developmental toxicity studies, 5 alpha-reductase inhibitors inhibited normal development of external genitalia in male fetuses.

Reproductivity

0.05 - 30 mg/kg/day Reproductivity, Embryo-fetal development study through oral doses administered during gestation

Result: Positive: Feminization of male fetuses

Species: Rabbit

0.05 - 500 mg/kg/day Fertility assessment

Result: Positive: Dose-dependant decrease in fertility

Species: Rat

0.5 mg/day Reproductivity, Embryo-fetal development study through oral doses

Result: Positive: Abnormalities of male genitalia in the fetus

Species: Rat

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Dutasteride (CAS 164656-23-9)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10 mg/l, 48 hours
Fish	NOEC	Fish	21 µg/l, 101 days Growth test

Persistence and degradability Not readily degradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
3.87, (pH 6)

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

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

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes
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SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
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US state regulations	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.
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International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	12-07-2012
Revision date	01-05-2018
Version #	02

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