DUTASTERIDE

MATERIAL SAFETY DATA SHEET

In accordance with Regulation (CE) 1907/2006, (CE) 1272/2008 and (EU) 453/2010 (Annex I)

Revision no. 4 - Revision date: April 5, 2012

SECTION 1.
IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Substance identifier

Substance name:	**DUTASTERIDE**
Other names (if available): Name in Annex VI-CLP: Name reported in the inventory of harmonized classification and labelling:	(5α,17β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-aza-androst-1-ene-17-carboxamide unlisted not available
CAS number	164656-23-9
REACH registration number	Exempt of registration

1.2. Relevant identified uses of the substance and uses advised against

Relevant use(s)	5-alpha reductase inhibitor API (Active Pharmaceutical Ingredient)
Uses advised against	none

1.3. Details of the supplier of the safety data sheet

Manufacturer/Distributor:
Company name: **STERLING S.r.l**
Address : **Via della Carboneria, 30 Solomeo**
06073 Corciano (PG) – Italy
Phone number : 075/5294001
Fax number: 075/5294000

Competent person responsible for the safety data sheet:
Aragona Anna Alessandra
e-mail: aragona@sterling.it

1.4. Emergency telephone number

02 66101029 (Centro Antiveleni Niguarda Ca' Granda – Milano)

SECTION 2
HAZARDS IDENTIFICATION

2.1 Classification of the substance

- **Classification of the substance in accordance with Regulation (CE) n. 1272/2008:**

Hazard class	Class code and hazard category	Hazard statement	Hazard warning
Reproductive toxicity	**Repr. Cat. 1B**	**H360FD**	**May damage fertility or the unborn child**
Carcinogenicity	**Carc. Cat. 2**	**H351**	**Suspected of causing cancer**

- **Classification in accordance with Directive 67/548/CEE :**

Classification	**Risk phrases**
Xn, R48/20/21/22	**Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.**
Carc. Cat 3, R40	**Limited evidence of a carcinogenic effect**
Repr. Cat 2, R60, R61	**May impair fertility** **May cause harm to the unborn child.**

Main adverse effects

Physico-chemical effects **No adverse effects known.**

Health effects **May damage fertility or the unborn child.** The most common adverse reactions reported in subjects receiving Dudasteride were impotence, decreased libido, breast disorders (including breast enlargement and tenderness), and ejaculation disorders. (2)

Environmental effects **No adverse effects known.**

See also sections from 9 to 12

2.2 Label elements

- **Labelling in accordance with regulation n. 1272/2008/EC**

Warning		
Signal Word	Danger	
Hazard indication (H))[1]	H351	H360FD
Safety statements (P)[1]	P201, P202, P281 P308+313 P405 P501	
- *Prevention*		
- *Reaction*		
- *Storage*		
- *Disposal*		

[1] For the explanation of H and P statements: see Section 16

2.3 Other hazards (which do not results in the classification)

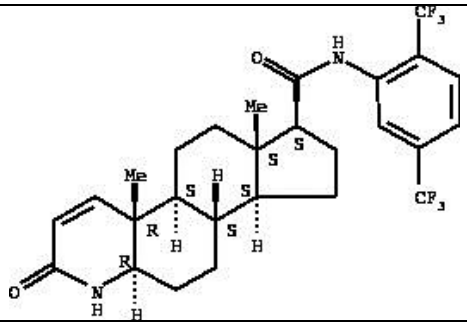
The substance satisfies the PBT criteria	YES	NO
- PBT		X
- vPvB		X

- Health hazards: May be harmful if ingested, inhaled or in contact with skin. Dudasteride is absorbed through the skin. May be irritant or sensitizer.
- Environmental hazards: not known
- Physico-chemical hazards: none

- Specific effects: unknown

SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS

Description: active pharmaceutical principle

Name of the component	Dutasteride
Concentration	Pure substance
Structural formula	
Chemical formula	$C_{27}H_{30}F_6N_2O_2$
Molecular weight	528,5 g/mol
Substance with Community OEL	No
CAS name	1H-Indeno[5,4-f]quinoline-7-carboxamide, 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-, (4aR,4bS,6aS,7S,9aS,9bS,11aR)-
CAS number	164656-23-9
IUPAC name	(1S,3aS,3bS,5aR,9aR,9bS,11aS)-N-[2,5-bis(trifluoromethyl)phenyl]-9a,11a-dimethyl-7-oxo-1,2,3,3a,3b,4,5,5a,6,9b,10,11-dodecahydroindeno[5,4-f]quinoline-1-carboxamide
EC number	638-758-5 (provisional)
Index number	not assigned
Impurity/ies (if classified)	-
Additive/ies (if classified)	-

SECTION 4
FIRST AID MEASURES

4.1 Description of the first aid measures

- Eye contact	Wash immediately with large amounts of water or normal saline. Keep eyelid open during the washing. Get medical advice if adverse symptoms will appear.
- Skin contact	Remove contaminated clothes (eventually shoes). Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains. Get medical advice if adverse symptoms will appear.
- Ingestion	If swallowed wash mouth with large amounts of water provided person is conscious. If victim is conscious and alert, give milk or water. Get medical advice if adverse symptoms will appear.
- Inhalation	Remove the person from the exposed area to fresh air immediately. If breathing has stopped perform artificial respiration, keep person warm and at rest. Get medical advice if the exposure was significant in terms of quantity or time.

4.2 Most important symptoms and effects (acute and delayed)

- Acute effects	Not known
- Delayed effects:	Suspected of causing cancer and damage fertility or the unborn child. The most common adverse reactions reported in subjects receiving Dutasteride were impotence, decreased libido, breast disorders (including breast enlargement and tenderness), and ejaculation disorders.

4.3 Indication of any immediate medical attention and special treatment needed

- Medical monitoring:	none
- Antidotes, if known	There is not a specific antidote for dutasteride.(2)
- Contraindications	unknow
- Immediate treatment at workplace	not known

SECTION 5
FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable estinguishing media	Water spray or chemical foam, dry foam, CO_2.
- Unsuitable estinguishing media	not known

5.2 Special hazards arising from the substance

- Hazardous combustion products	May generate toxic fumes of COx, NOx and compounds containing fluorine.
- Other special hazards	not known

5.3 Advice fo firefighters

- Technical actions for protection	Keep containers cool with water.
- Special protective equipment for firefighters	Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections

SECTION 6
ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel
Wear appropriate protective equipment (see Section 8) to prevent contamination of the skin, eyes and personal clothing.
In case of fire and/or and explosions avoid breathing fumes and vapors. Use a self-contained breathing apparatus (SCBA) and appropriate protective clothing. The fumes can be eliminated by spraying with water.
See also section 8

- **For emergency responders**
See section 8.

6.2 Environmental precautions

In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water. Contact local authorities in case of environmental release.

6.3 Methods and material for containment and clearing up

- *Containment procedures:*	Coverage of the discharges
- *Cleaning up procedures:*	Recover the substance for suction or other mechanical means and wash the area with plenty of water and detergents. Store the material into a company that specializes pending disposal. Containers must be cleaned up and disposed of as waste remediation above.

6.4 Reference to other sections

See also section 8 and 13.

SECTION 7
HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Recommandation for handling:*	Handle away from sparkles and flames - sources of ignition Handle in a well ventilated place Avoid contact with incompatible materials Wear suitable Personal Protection Equipment (see section 8) Keep the substance away from drains, surface or ground waters
- *Recommandation for personal hygiene:*	Do not absolutely eat, drink and smoke in the working areas Wash hands after handling the substance Remove contaminated clothing and protective equipment before entering eating areas

7.2. Condition for safe storage including any incompatibilities

The substance is not classified for any physical and chemical properties and no risk management is foreseen.

Other advice

	Store at controlled room temperature
- *Ventilation requirements*	Use in a well ventilated place at room temperature (not more than 25 °C)
- *Containers*	Keep containers tightly closed and correctly labelled
- *Specific design of storage rooms*	Not requested on the base of the classification
- *Quantity limits for storage*	Not requested on the base of the classification
- *Packaging compatibilities*	See also section 10.5

7.3. Specific end use(s)

- Recommendation for specific final use(s): Active Pharmaceutical Principle

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Industry or sector specific guidance available and attached		X

SECTION 8
EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- National/European Occupational Exposure Limits	unknow
- Other National/European Occupational Exposure Limits	unknow
- Recommended monitoring procedures	The measurement of substances in the workplace must be carried out with standardized methods (eg EN 689:1997: Workplace atmospheres - Guide for assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; UNI EN 482:2006: atmospheres in the workplace - General requirements for the provision of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.
- DNEL values (components)	unknow
- PNEC values (components)	unknow

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

8.2.1. Appropriate engineering controls

The adoption of the most appropriate technical controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance) when a unique and standardized exposure scenario described in a dossier registered REACH is not available.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

a) Eye and Face protection	Safety goggles as for EN 166; facial shield
b) Skin protection	
- *hands protection*	Wear protective gloves.

	Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/CEE. The glove material has to be made of rubber or polyethylene impermeable and resistant to the substance. Make the choice of the glove material on consideration of the penetration times, rates of diffusion and degradation. The selection of suitable gloves not only depends on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- *other, body protection*	Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 13982.
c) Respiratory protection	Dust mask with approved dust filter. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU) In the case of brief exposure or minimal exposure use respiratory filter; in case of intensive and sustained exposition wear self-contained breathing.
d) Thermal hazards	Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 9
PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	white solid (crystallin powder)
Odor:	odourless
Odour threshold:	-
pH:	Data not available in the literature search carried out
Melting point/freezing point:	242 - 250°C (2)
Boiling point:	620.3 °C at 760 mmHg (predicted) (1)
Flash point:	329 °C (predicted) (1)
Auto-ignition temperature:	Data not available in the literature search carried out
Surface tension:	38.1 dyne/cm (predicted) (1)
Density:	1.303 g/cm^3 (predicted) (1)
Vapour pressure:	2.59 x 10^{-15} mmHg at 25°C
Relative density:	1,303 ± 0,06 g/cm³
Water solubility:	Not soluble (2)
Organic solvent solubility:	soluble in ethanol (44 mg/ml), methanol (64 mg/ml) and Polyethylene glycol 400 (3 mg/ml) (2)
Partition coefficient Octonol/water (Log Kow):	5.61 (predicted) (1)
Explosive properties:	Data not available in the literature search carried out
Oxidising properties:	Data not available in the literature search carried out

9.2. Other information

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SECTION 10
STABILITY AND REACTIVITY

10.1. Reactivity

Stable in normal conditions of storage.

10.2. Chemical stability

The substance is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.

	NO	YES	Used stabiliser
- Stabilisers:	X	-	
- Change in physical appearance	X	-	

10.3. Possibility of hazardous reactions

	NO	YES
- Possibility of an exothermic reaction:	X	-
- Possibility of a reaction releasing excessive pressure	X	-
- Possible degradation with instable product formation	X	-

10.4. Condition to avoid

Keep protected from light, humidity and high temperatures.

10.5. Incompatible materials

Strong oxidizing agents

10.6. hazardous decomposition products

If heated at high temperatures, decomposes re leasing fumes and toxic gases of COx, NOx and compounds containing fluorine.

SECTION 11
INFORMATION ON TOXICOLOGICAL EFFECTS

- **Exposure routes:**	YES	NO
- Inhalation:	X	
- Ingestion:	X	
- Skin contact:	X	

- Eye contact:	X	

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- Inhalation:	Suspected of causing cancer, may be damage fertility or the unborn child may be harmful or sensitizing by inhalation
- Ingestion:	May be harmful if swallowed
- Skin contact:	May be irritant or sensitizing. Dutasteride is absorbed through the skin.
- Eye contact:	May be irritant

-Toxico-kinetics information (ADME=Adsorption,**D**istribution,**M**etabolism,**E**xcretion**):** [2]

Absorption**:** Following administration of a single 0.5-mg dose of a soft gelatin capsule, time to peak serum concentrations (T_{max}) of dutasteride occurs within 2 to 3 hours. Absolute bioavailability in 5 healthy subjects is approximately 60% (range, 40% to 94%).

Distribution**:** Pharmacokinetic data following single and repeat oral doses show that dutasteride has a large volume of distribution. Dutasteride is highly bound to plasma albumin (99.0%) and alpha-1 acid glycoprotein (96.6%).

Metabolism and Elimination**:** Dutasteride is extensively metabolized in humans. In vitro studies showed that dutasteride is metabolized by the CYP3A4 and CYP3A5 isoenzymes.

In human serum following dosing to steady state, unchanged dutasteride, 3 major metabolites and 2 minor metabolites have been detected. Dutasteride and its metabolites were excreted mainly in feces. Approximately 5% unchanged dutasteride and 40% as dutasteride-related metabolites. Only trace amounts of unchanged dutasteride were found in urine (<1%).

Due to the long half-life of dutasteride, serum concentrations remain detectable (greater than 0.1 ng/mL) for up to 4 to 6 months after discontinuation of treatment.

Dutasteride is secreted into male semen.

- Acute toxicity effects:

- Oral:	Data not available in the literature search carried out
- Dermal:	Data not available in the literature search carried out
- Inhalation:	Data not available in the literature search carried out
- Other effects:	-

- Corrosion/Irritation effects: Data not available in the literature search carried out

- Severe ocular lesion *:* Data not available in the literature search carried out

- Sensitisation:

- Dermal:	Data not available in the literature search carried out
- Respiratory:	Data not available in the literature search carried out

- Repeated dose toxicity (experimental.): In rats and dogs, repeated oral administration of dutasteride resulted in some animals showing signs of non-specific, reversible, centrally-mediated toxicity without associated histopathological changes at exposure 425- and 315-fold the expected clinical exposure (of parent drug), respectively. [2]
NOAEL is not available in the literature search carried out

- CMR effects:

- **Germinal cell mutagenicity**[2]: Ames test: negative
  Chromosomal aberration: negative
  Micronucleus test: negative
  Two major human metabolites were also negative in either the Ames test or an abbreviated Ames test.

- **Carcinogenicity**[2]:

A 2-year carcinogenicity study was conducted in mice at doses of 3, 35, 250, and 500 mg/kg/day for males and 3, 35, and 250 mg/kg/day for females; an increased incidence of benign hepatocellular adenomas was noted at 250 mg/kg/day in females only.

In a 2-year carcinogenicity study in Han Wistar rats, at doses of 1.5, 7.5, and 53 mg/kg/day for males and 0.8, 6.3 and 15 mg/kg/day for females, there was an increase in Leydig cell adenomas in the testes at 53 mg/kg/day. An increased incidence of Leydig cell hyperplasia was present at 7.5 mg/kg/day (52-fold the expected clinical exposure) and 53 mg/kg/day in male rats. A positive correlation between proliferative changes in the Leydig cells and an increase in circulating luteinizing hormone levels has been demonstrated with 5α-reductase inhibitors and is consistent with an effect on the hypothalamic-pituitary testicular axis following 5α-reductase inhibition.

- **Reproductive toxicity**[2]: In animal reproduction and developmental toxicity studies, dutasteride inhibited development of male fetus external genitalia. Therefore, Dutasteride may cause fetal harm when administered to a pregnant woman. If it is used during pregnancy or if the patient becomes pregnant while taking Dutasteride, the patient should be apprised of the potential hazard to the fetus. Pregnancy category X.
Embryo-fetal development study in female rats, oral administration of dutasteride at doses 10 times less than the maximum recommended human dose (MRHD) resulted in abnormalities of male genitalia in the fetus, and nipple development, hypospadias and distended preputial glands in male offspring. An increase in stillborn pups was observed at 111 times the MRHD and reduced fetal body weight was observed at doses ≥15 times the MRHD. Increased incidences of skeletal variations considered to be delays in ossification associated with reduced body weight were observed at doses ≥56 times the MRHD.
Abnormalities of male genitalia were also observed in an oral pre- and post-natal development study in rats and in 2 embryo-fetal studies in rabbits at one-third the MRHD.

- **Impairment of fertility** [2]: Treatment of sexually mature male rats with dutasteride at doses of 0.05, 10, 50, and 500 mg/kg/day (0.1- to 110-fold the expected clinical exposure of parent drug) for up to 31 weeks resulted in dose and time-dependent decreases in fertility; reduced cauda epididymal (absolute) sperm counts but not sperm concentration (at 50 and 500 mg/kg/day); reduced weights of the epididymis, prostate, and seminal vesicles and microscopic changes in the male reproductive organs. The fertility effects were reversed by recovery week 6 at all doses, and sperm counts were normal at the end of a 14-week recovery period.
In a fertility study in female rats, oral administration of dutasteride at doses of 0.05, 2.5, 12.5, and 30 mg/kg/day resulted in reduced litter size, increased embryo resorption and feminization of male fetuses (decreased anogenital distance) at doses of ≥2.5 mg/kg/day (2- to 10-fold the clinical exposure of parent drug in men). Fetal body weights were also reduced at ≥0.05 mg/kg/day in rats (<0.02-fold the human exposure).

- Specific Target Organ Toxicity (STOT)-single exposure:

Data not available in the literature search carried out

- Specific Target Organ Toxicity (STOT)- repeated exposure :

Data not available in the literature search carried out

- Aspiration hazards: Data not available in the literature search carried out

- Epidemiological information: [2]
The effects of dutasteride 0.5 mg/day on semen characteristics were evaluated in normal volunteers aged 18 to 52 (n = 27 dutasteride, n = 23 placebo) throughout 52 weeks of treatment and 24 weeks of post-treatment follow-up.It was observed reduction in total sperm count, semen volume, and sperm motility. The clinical significance of dutasteride's effect on semen characteristics for an individual patient's fertility is not known.

SECTION 12
ECOLOGICAL INFORMATION

12.1. Toxicity

Data not available in the literature search carried out

12.2. Persistence and degradability

BCF : 10784.39 (predicted by ACS/Lab) (1)

12.3. Bioaccumulative potential

LogPow = 5.61 (1)

12.4. Mobility in soil

Data not available in the literature search carried out

12.5. Results of PBT e vPvB assessment

Assessment is not available - in relation to the logPow and BCF predicted values a low bioaccumulation potential is expected.

12.6. Other adverse effects

Not known

SECTION 13
DISPOSAL CONSIDERATION

13.1. Waste treatment methods

	Incineration	Recycling	Landfilling
- Mixture wastes:	X		
- Contaminated packaging:		X	

Should never be disposed through wastewater.
Refers to Community/National/Local requirements concerning the waste disposal.

SECTION 14
TRANSPORT INFORMATION

The substance is not classified for transport.

SECTION 15
REGULATORY INFORMATION

15.1 Safety, Health and Environmental regulation/legislation specific for the mixture or its ingredients

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and following amendment and National reinforcements.

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 - 0023

Regulation (EC) no 689/2008 of the european parliament and of the council of 17 June 2008 concerning the export and import of dangerous chemicals

15.2. Chemical Safety Assessment

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 16
OTHER INFORMATION

Revisions:

- **Revision n. 03 dated** January 2011 (regarding all sections in according to Regulation no. 453/2010).

Bibliographic sources:

(1) Chemspider data base, search for Dutasteride
(2) Daily Med, Current Medication Information, AVODART (dutasteride) capsule, liquid filled

Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative

Information related to the regulation CE/1272/2008

List of hazards statements

H351:	**Suspected of causing cancer**
H360FD:	**May damage fertility or the unborn child**

List of P statements

Prevention

P201	**Obtain special instructions before use.**
P202	**Do not handle until all safety precautions havebeen read and understood.**
P281	**Use personal protective equipment as required.**

Reaction

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

Storage

P405	**Store locked up.**

Disposal

P501:	**Dispose of contents/container in accordance with local/regional/national/ international regulation.**

Information related to the Directive 67/ 548/ CEE, Directive 1999/45/CE and Regulation (CE) n. 1907/2006

R phrases

R48/20/21/22:	**Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.**
R40:	**Limited evidence of a carcinogenic effect.**
R60:	**May impair fertility.**
R61:	**May cause harm to the unborn child.**

Information on workers training

Follow criteria of Directive 98/24/CE, its amendments and National reinforcements

Restriction of use : None

Substance under authorisation : no

DISCLAIMER

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