

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



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

1.1 Product identifier

Product name: Dutasteride
Dutasteridum
Dutasteride
Dutastéride
Dutasterid
N° CAS: 164656-23-9
N° EC: 638-758-5

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium
Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Repr. 1B	H360
Aquatic Chronic 1	H410
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H360	May damage fertility or the unborn child.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



DUTASTERIDUM

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P273	Avoid release to the environment.
P281	Use personal protective equipment as required.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/container to a waste disposal plant in accordance with local, regional, national and/or international regulations.

Additional applicable label elements: Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dutasteride
IUPAC name:	(5 α ,17 β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-aza-androst-1-ene-17-carboxamide
Synonyms:	Avodart Avolve
N° CAS:	164656-23-9
N° EC:	638-758-5
Molecular Formula:	C ₂₇ H ₃₀ F ₆ N ₂ O ₂
Content:	97.0 per cent to 102.0 per cent (anhydrous substance)

3.2 Mixtures

It contains no other components or impurities that may influence the classification of the product.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Remove to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



4.2 Most important symptoms and effects, both acute and delayed

Ingestion of even a small amount of this product poses a serious health risk. Suspected of damaging the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to an unconscious person.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water fog.
Neighbouring fires (containers exposed to fire): Water spray or water mist.

Unsuitable extinguishing media: Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.

Protection against fire: Helmet with visor, fireproof clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or self (self protective) in the case of large quantities of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8. Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

For emergency responders

For exposure control and personal protective measures, see section 8. Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2 Environmental precautions

Prevent release to the environment. Prevent entry into sewers and watercourses. If product enters drains or public waterways, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Wash thoroughly after handling. Do not eat, drink or smoke while handling this product. Ask for special instructions before use.
Personal protection:	Not available.
Technical protective measures:	Ensure good ventilation of the processing area to avoid vapour formation.
Handling:	Wash thoroughly after handling. Do not eat, drink or smoke while handling this product.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Not available.
Conditions for safe storage, including any incompatibilities:	Keep only in the original container in a cool, well-ventilated place. Keep container closed when not in use.
Storage – away from:	Store away from strong bases, strong acids, sources of ignition and direct sunlight.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection:	Protective face shields and safety goggles according to EN166.
Skin protection:	Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.
Hand protection:	Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or pale yellow powder.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point:	620 °C
Boiling range:	Not available.
Flash point:	329 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in methylene chloride, soluble or sparingly soluble in anhydrous ethanol.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molecular weight:	528.53 g/mol
Density (20 °C):	1.303 g/mL

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid

Avoid any improper handling: high pressures and/or high temperatures. Direct sunlight.

10.5 Incompatible materials

Strong acids and strong bases.

10.6 Hazardous decomposition products

Decomposition by heat may produce toxic fumes of CO, CO₂ and NO_x.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀, rat): > 2000 mg/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1%.

Reproductive toxicity: Not available.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: RTECS N°: NK94666000

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

Skin contact: Not available.

Inhalation: Not available.

Ingestion: Not available.

Aspiration: Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity (EC₅₀): > 1 mg/L (*Daphnia magna*)

12.2 Persistence and degradability

May cause long-term adverse effects in the environment.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : It is not dangerous in transport.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



14.6 Special precautions for user

It is not dangerous in transport.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R60 May impair fertility.

R61 May cause harm to the unborn child.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases:

S53 Avoid exposure - obtain special instructions before use.

S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity

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DUTASTERIDUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 12/10/2022

Revision: 03/07/2024

Version: 01



UN (number): United Nations (number)
vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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