

Dutasteride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 08/07/2025 Supersedes version of: 03/04/2023 Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Dutasteride
Chemical name : Dutasteride
CAS-No. : 164656-23-9
Product code : 201600330

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Endocrine disruptor for the environment, Category 1 EUH430
Endocrine disruptor for human health, Category 1 EUH380
Reproductive toxicity, Category 1A H360
Specific target organ toxicity – Repeated exposure, Category 2 H373
Hazardous to the aquatic environment – Chronic Hazard, H410
Category 1

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Very toxic to aquatic life with long lasting effects. May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS08

GHS09

Signal word (CLP) : Danger

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- Hazard statements (CLP) : EUH380 - May cause endocrine disruption in humans.
EUH430 - May cause endocrine disruption in the environment.
H360 - May damage fertility or the unborn child.
H373 - May cause damage to organs (endocrine system) through prolonged or repeated exposure.
H410 - Very toxic to aquatic life with long lasting effects.
- Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P263 - Avoid contact during pregnancy and while nursing.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P314 - Get medical advice/attention if you feel unwell.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS08

2.3. Other hazards

The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

- Other information : Active substance (in pharmaceutical products).
Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Dutasteride substance identified as having endocrine disrupting properties	CAS-No.: 164656-23-9	≤ 100	ED ENV 1, EUH430 ED HH 1, EUH380 Repr. 1A, H360 STOT RE 2, H373 Aquatic Chronic 1, H410

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

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First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Do not expose pregnant or breastfeeding women.
Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white. Pale yellow.
Appearance	: Powder.
Molecular mass	: 528.5 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 242 – 250 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l

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Partition coefficient n-octanol/water (Log Kow)	: 3.87
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Lack of data)

Dutasteride (164656-23-9)	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: May cause damage to organs (endocrine system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

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11.2. Information on other hazards

Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.

Dutasteride (164656-23-9)

EC50 - Crustacea [1]	> 1 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method)
NOEC chronic fish	0.021 mg/l (101 days, Juvenile Pimephales promelas) (OECD 210 method)

12.2. Persistence and degradability

Dutasteride (164656-23-9)

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

Dutasteride (164656-23-9)

Partition coefficient n-octanol/water (Log Kow)	3.87
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : Has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information



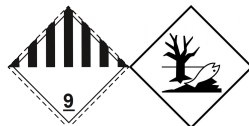
In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077

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ADR	IMDG	IATA
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9
		
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 
Tunnel restriction code (ADR)	: -

Transport by sea

Special provisions (IMDG)	: 274, 335, 375, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002

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Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes

Section	Changed item	Comments
	UN-No. (RID)	Added
	Number of blue cones/lights (ADN)	Added

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Indication of changes		
Section	Changed item	Comments
	Equipment required (ADN)	Added
	Carriage permitted (ADN)	Added
	Excepted quantities (ADN)	Added
	Limited quantities (ADN)	Added
	Danger labels (ADN)	Added
	Classification code (ADN)	Added
	Proper Shipping Name (RID)	Added
	Hazard identification number (RID)	Added
	Colis express (express parcels) (RID)	Added
	Special provisions for carriage - Loading, unloading and handling (RID)	Added
	Special provisions for carriage – Bulk (RID)	Added
	Special provisions for carriage – Packages (RID)	Added
	Transport category (RID)	Added
	Tank codes for RID tanks (RID)	Added
	Portable tank and bulk container special provisions (RID)	Added
	Portable tank and bulk container instructions (RID)	Added
	Mixed packing provisions (RID)	Added
	Special packing provisions (RID)	Added
	Packing instructions (RID)	Added
	Excepted quantities (RID)	Added
	Limited quantities (RID)	Added
	Special provisions (RID)	Added
	Packing group (RID)	Added
	Classification code (RID)	Added
	ERG code (IATA)	Added
	Special provisions (IATA)	Added
	CAO max net quantity (IATA)	Added
	CAO packing instructions (IATA)	Added
	PCA max net quantity (IATA)	Added
	PCA packing instructions (IATA)	Added
	PCA limited quantity max net quantity (IATA)	Added
	PCA Limited quantities (IATA)	Added
	PCA Excepted quantities (IATA)	Added
	Danger labels (IATA)	Added
	Proper Shipping Name (IATA)	Added

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Indication of changes		
Section	Changed item	Comments
	Proper Shipping Name (IMDG)	Added
	Danger labels (IMDG)	Added
	EmS-No. (Spillage)	Added
	EmS-No. (Fire)	Added
	Limited quantities (IMDG)	Added
	Stowage and handling (IMDG)	Added
	Stowage category (IMDG)	Added
	Tank special provisions (IMDG)	Added
	Tank instructions (IMDG)	Added
	IBC special provisions (IMDG)	Added
	IBC packing instructions (IMDG)	Added
	Excepted quantities (IMDG)	Added
	Special provisions (IMDG)	Added
	Special provisions for carriage - Loading, unloading and handling (ADR)	Added
	Special provisions for carriage - Bulk (ADR)	Added
	Special provisions for carriage - Packages (ADR)	Added
	Tank code (ADR)	Added
	Portable tank and bulk container special provisions (ADR)	Added
	Portable tank and bulk container instructions (ADR)	Added
	Mixed packing provisions (ADR)	Added
	Special packing provisions (ADR)	Added
	Packing instructions (ADR)	Added
	Vehicle for tank carriage	Added
	Supersedes version of	Added
	Revision date	Added
1.1	CAS-No.	Added
1.1	Synonyms	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified

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Indication of changes		
Section	Changed item	Comments
2.2	Hazard pictograms (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects	Removed
4.2	Symptoms/effects after ingestion	Removed
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Removed
4.3	Other medical advice or treatment	Removed
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.1	General measures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Modified
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.2	Storage conditions	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.3	Specific end uses	Removed
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Eye protection	Modified
8.2	Appropriate engineering controls	Modified

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Indication of changes		
Section	Changed item	Comments
8.2	Skin and body protection	Modified
9	Molecular mass	Added
9	Colour	Added
9	Melting point	Added
9	Partition coefficient n-octanol/water (Log Kow)	Added
9	Odour	Removed
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Added
11.1	LD50 dermal rabbit	Added
11.1	ATE CLP (oral)	Removed
12.1	NOEC chronic fish	Added
12.1	EC50 - Crustacea [1]	Added
12.1	Ecology - general	Removed
13.1	Regional waste regulation	Removed
14.1	UN-No. (ADN)	Added
14.1	UN-No. (IMDG)	Added
14.1	UN-No. (IATA)	Added
14.1	UN-No. (ADR)	Added
14.2	Proper Shipping Name (ADN)	Added
14.2	Proper Shipping Name (ADR)	Added
14.3	Danger labels (RID)	Added
14.3	Danger labels (ADR)	Added
14.3	Class (ADR)	Added
14.4	Packing group (ADN)	Added
14.4	Packing group (IATA)	Added
14.4	Packing group (IMDG)	Added
14.4	Packing group (ADR)	Added
14.6	Additional requirements/Remarks (ADN)	Added
14.6	Special provisions (ADN)	Added
14.6	Special packing provisions (IMDG)	Added
14.6	Packing instructions (IMDG)	Added
14.6	Transport category (ADR)	Added
14.6	Special provisions (ADR)	Added
14.6	Excepted quantities (ADR)	Added
14.6	Limited quantities (ADR)	Added
14.6	Tunnel restriction code (ADR)	Added

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Indication of changes		
Section	Changed item	Comments
14.6	Hazard identification number (Kemler No.)	Added
14.6	Classification code (ADR)	Added

Full text of H- and EUH-statements:	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
ED ENV 1	Endocrine disruptor for the environment, Category 1
ED HH 1	Endocrine disruptor for human health, Category 1
EUH380	May cause endocrine disruption in humans.
EUH430	May cause endocrine disruption in the environment.
H360	May damage fertility or the unborn child.
H373	May cause damage to organs (endocrine system) through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Safety Data Sheet (SDS), EU

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