

Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 1 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126



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

1.1. Product identifier

Product name: **DUTASTERIDA (EUR. PH.)**
Product code: 009709
N° CAS: 164565-23-9
N° EC: 638-758-5

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

Relevant identified uses: Active pharmaceutical ingredient

1.3. Details of the supplier of the safety data sheet

Company: **METAPHARMACEUTICAL INDUSTRIAL SLU**
JOSEP PLA 163 2º 5ª
08020 BARCELONA
SPAIN
Phone number: (0034) 933 089 976
Contact e-mail: info@metaph.es
Web page: www.metaph.com

1.4. Emergency telephone number

National Institute of Toxicology of Madrid: (0034) 915 620 420

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP).
Repr. 1B, H360
Aquatic Chronic 1, H410

2.2. Label Elements



Signal word (CLP): DANGER

Hazard statements (CLP)

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

Precautionary statements (CLP)

P273: Avoid release to the environment
P280: Wear protective gloves/protective clothing/eye protection/face protection
P391: Collect spillage
P308+P313: IF exposed or concerned: Get medical advice/attention
P405: Store locked up
P501: Dispose of the contents/container at a waste disposal facility in accordance with local, regional, national, and/or international regulations

Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 2 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126

**2.3. Other hazards**

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Substances**

Product name:	DUTASTERIDA
Synonyms:	DUTASTERIDE, DUTASTERIDA
IUPAC name:	(5 α ,17 β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-aza-androst-1-ene-17-carboxamide
N ^o CAS:	164565-23-9
N ^o EC:	638-758-5
Molecular formula:	C ₂₇ H ₃₀ F ₆ N ₂ O ₂

3.2. Mixtures

Not applicable.

4. FIRST AID MEASURES**4.1. Description of first aid measures**

General advises:	Consult a doctor. Show the safety data sheet to the doctor on duty.
Inhalation:	Take outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
Skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
Eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion:	If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

Ingestion of a small quantity of this product may pose a serious health risk. Suspected of damaging the unborn child.

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

Get medical advice/attention. If possible, show this sheet, if not available show packaging or label.

5. FIREFIGHTING MEASURES**5.1. Extinguishing media**

Suitable extinguishing methods:	Foam, dry powder, carbon dioxide, sand, water mist
Unsuitable extinguishing methods:	Direct water jet.
Neighboring fires (containers exposed to fire):	Atomized or nebulized water.

5.2. Special hazards arising from the substance or mixture

In the event of a fire, fumes harmful to health may be generated.

Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 3 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126

**5.3. Advice for firefighters**

General information: Cool containers with water to prevent product decomposition and development of potential health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Equipment: Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms, legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

6. ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapors/spray. Wear suitable protective clothing, gloves and eye or face protection.

6.2. Environmental precautions

Avoid getting into sewers and water pipes. If the product reaches drains or public water pipes, notify the authorities.

6.3. Methods and material for containment and cleaning up

Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with: Sodium hypochlorite solution.

6.4. Reference to other sections

No additional information available.

7. HANDLING AND STORAGE**7.1. Precautions for safe handling**

Avoid dispersion of the product into the environment. Smoking, eating, and drinking must be prohibited in the application area. Comply with occupational safety and hygiene regulations. Store the product in containers made of material identical to the original.

7.2. Conditions for safe storage, including any incompatibilities

Keep only in the original container in a cool, well-ventilated place. Keep the container tightly closed when not in use. Store away from strong bases, strong acids, sources of ignition, and direct sunlight.

7.3. Specific end use(s)

No additional information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Exposure controls/personal protection**

No additional information available.

8.2. Exposure controls

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.



Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 4 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126



Eye and face protection:	Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.
Hands protection:	Handle with gloves. The selected protective gloves must comply with the specifications of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN 420 derived from it.
Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, use type N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN (EU).
Skin protection:	Choose body protection based on the amount and concentration of the dangerous substance in the workplace.
Hygiene measures:	Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect:	Crystalline powder
Color:	White or almost white
Odor:	Characteristic
Molecular Weight (g/mol):	528.53
Boiling Point (°C):	620
Ignition temperature (°C):	329

9.2. Other information

No additional information available.

10. STABILITY AND REACTIVITY

10.1. Reactivity

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

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Not available.

10.4. Conditions to avoid

Avoid any improper handling, including exposure to high pressures and/or elevated temperatures. Protect from direct sunlight.

10.5. Incompatible materials

Strong acids and bases.

10.6. Hazardous decomposition products

Thermal decomposition may generate toxic fumes containing carbon monoxide (CO), carbon dioxide (CO₂), and nitrogen oxides (NO_x).

Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 5 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126



11. TOXICOLOGICAL INFORMATION

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

Acute oral toxicity (LD50, rat):	> 2000 mg/Kg
Skin corrosion/irritation:	No additional information available (Lack of data)
Serious eye damage/eye irritation:	No additional information available (Lack of data)
Skin or respiratory sensitization:	No additional information available (Lack of data)
STOT – single exposure:	No additional information available (Lack of data)
STOT – repeated exposure:	No additional information available (Lack of data)
Carcinogenicity:	Suspected of damaging the unborn child. Suspected of impairing fertility.
Reproductive toxicity:	No additional information available (Lack of data)
Germ cell mutagenicity:	No additional information available (Lack of data)
Aspiration Hazard:	No additional information available (Lack of data)

Potential Health Effects

Inhalation:	No additional information available (Lack of data)
Ingestion:	No additional information available (Lack of data)
Skin:	No additional information available (Lack of data)
Eyes:	No additional information available (Lack of data)
Signs and Symptoms of Exposure:	No additional information available (Lack of data)

11.2. Information on other hazards

Nº RTECS: NK94666000

12. ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

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

No additional information available.

12.4. Results of PBT and vPvB assessment

No additional information available.

12.5. Other adverse effects

Avoid release to the environment.

Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 6 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126



13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service to dispose 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.

14. INFORMACIÓN RELATIVA AL TRANSPORTE

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

14.1. UN Number

Not classified as dangerous for transport.

14.2. UN proper shipping name

No additional information available.

14.3. Transport hazard class(es)

No additional information available.

14.4. Packing group

No additional information available.

14.5. Environmental hazards

No additional information available.

14.6. Special precautions for user

No additional information available.

14.7. Maritime transport in bulk according to IMO instruments

No additional information available.

15. REGULATORY INFORMATION

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

The Safety Data Sheet complies with the requirements of Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council is modified, relating to the registration, evaluation, authorization and restriction of chemical substances and mixtures (REACH).

15.2. Chemical safety assessment

No additional information available.

Product: **DUTASTERIDA (EUR. PH.)**

Product code: 009709

Page 7 of 7

Emission date: 28/11/2025

Version: 009709_MSDS_ENG_0126

**16. OTHER INFORMATION****Abbreviations and acronyms:**

PBT: Persistent, bioaccumulative and toxic
mPmB: Very persistent and very bioaccumulative
REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

Data sources used:

Regulation (CE) No. 1272/2008 of the European Parliament and of the Council, of December 16, 2008, on the classification, labeling and packaging of substances and mixtures, and by which Directives 67/548/CEE and 1999 are modified and repealed /45/CE and modifies Regulation (CE) No. 1907/2006.

Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, regarding registration, evaluation, authorization and the restriction of chemical substances and mixtures (REACH)

Safety Data Sheet according to Annex II of REACH Regulation (EU) 2020/878**Department issuing the Safety Data Sheet:**

Technical Department

The information in this Product Safety Data Sheet is based on current knowledge and current EC and national laws, as far as the working conditions of users are beyond our knowledge and control. The product must not be used for purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in the legislation.