

Creation Date 18-Apr-2016

Revision Date 18-Apr-2016

Revision Number 1

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

### 1.1. Product identification

Product Description: **Dutasteride**  
 Cat No. : **461510000; 461510010; 461512500**  
 CAS-No **164656-23-9**  
 Molecular Formula **C<sub>27</sub> H<sub>30</sub> F<sub>6</sub> N<sub>2</sub> O<sub>2</sub>**

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

Recommended Use Laboratory chemicals.  
 Uses advised against No Information available

### 1.3. Details of the supplier of the safety data sheet

Company Acros Organics BVBA  
 Janssen Pharmaceuticaaan 3a  
 2440 Geel, Belgium  
 E-mail address begel.sdsdesk@thermofisher.com

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

#### Physical hazards

Based on available data, the classification criteria are not met

#### Health hazards

Reproductive Toxicity Category 1B

#### Environmental hazards

Chronic aquatic toxicity Category 3

### 2.2. Label elements

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016



**Signal Word**

**Danger**

## **Hazard Statements**

H360Df - May damage the unborn child. Suspected of damaging fertility  
H412 - Harmful to aquatic life with long lasting effects

## **Precautionary Statements**

P201 - Obtain special instructions before use  
P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection  
P308 + P313 - IF exposed or concerned: Get medical advice/ attention

## **Additional EU labelling**

Restricted to professional users

## **2.3. Other hazards**

No information available

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### **3.1. Substances**

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Dutasteride	164656-23-9		>95	Repr. 1B (H360Df) Aquatic Chronic 3 (H412)

Full text of Hazard Statements: see section 16

## **SECTION 4: FIRST AID MEASURES**

### **4.1. Description of first aid measures**

#### **General Advice**

If symptoms persist, call a physician.

#### **Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

#### **Skin Contact**

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

#### **Ingestion**

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

#### **Inhalation**

Move to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

#### **Protection of First-aiders**

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

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

None reasonably foreseeable.

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

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

### Notes to Physician

Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

#### Suitable Extinguishing Media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### Extinguishing media which must not be used for safety reasons

No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### Hazardous Combustion Products

Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Fluorine compounds.

### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

### 6.2. Environmental precautions

Should not be released into the environment. Do not flush into surface water or sanitary sewer system.

### 6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Wash hands before breaks and at the end of workday.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality: Store in freezer.

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

## 7.3. Specific end use(s)

Use in laboratories

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

#### Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

#### Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available

Route of exposure	Acute effects (local)	Acute effects (systemic)	Chronic effects (local)	Chronic effects (systemic)
Oral				
Dermal				
Inhalation				

**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2. Exposure controls

#### Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

#### Personal protective equipment

##### Eye Protection

Safety glasses with side-shields (European standard - EN 166)

##### Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
Neoprene	recommendations			
Natural rubber				
PVC				

##### Skin and body protection

Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

<b>Respiratory Protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly
<b>Large scale/emergency use</b>	Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced <b>Recommended Filter type:</b> Particulates filter conforming to EN 143
<b>Small scale/Laboratory use</b>	Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. <b>Recommended half mask:-</b> Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted
<b>Environmental exposure controls</b>	Prevent product from entering drains.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	White to yellow	
<b>Physical State</b>	Solid	
<b>Odor</b>	No information available	
<b>Odor Threshold</b>	No data available	
<b>pH</b>	No information available	
<b>Melting Point/Range</b>	245 °C / 473 °F	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No information available	
<b>Flash Point</b>	No information available	<b>Method -</b> No information available
<b>Evaporation Rate</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available	
<b>Explosion Limits</b>	No data available	
<b>Vapor Pressure</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Specific Gravity / Density</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Water Solubility</b>	Insoluble	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Autoignition Temperature</b>	Not applicable	
<b>Decomposition Temperature</b>	No data available	
<b>Viscosity</b>	Not applicable	Solid
<b>Explosive Properties</b>	No information available	
<b>Oxidizing Properties</b>	No information available	

### 9.2. Other information

<b>Molecular Formula</b>	C27 H30 F6 N2 O2
<b>Molecular Weight</b>	528.53

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

None known, based on information available

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

## 10.2. Chemical stability

Stable under normal conditions

## 10.3. Possibility of hazardous reactions

### Hazardous Polymerization

No information available.

### Hazardous Reactions

None under normal processing.

## 10.4. Conditions to avoid

Incompatible products. Excess heat.

## 10.5. Incompatible materials

Strong oxidizing agents.

## 10.6. Hazardous decomposition products

Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Fluorine compounds.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### Product Information

#### (a) acute toxicity;

Oral

No data available

Dermal

No data available

Inhalation

No data available

#### (b) skin corrosion/irritation;

No data available

#### (c) serious eye damage/irritation;

No data available

#### (d) respiratory or skin sensitization;

Respiratory

No data available

Skin

No data available

#### (e) germ cell mutagenicity;

No data available

#### (f) carcinogenicity;

No data available

There are no known carcinogenic chemicals in this product

#### (g) reproductive toxicity;

Category 1B

#### (h) STOT-single exposure;

No data available

#### (i) STOT-repeated exposure;

No data available

Target Organs

None known.

#### (j) aspiration hazard;

Not applicable

Solid

Symptoms / effects, both acute and delayed No information available

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

<b>Ecotoxicity effects</b>	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. The product contains following substances which are hazardous for the environment.
<b><u>12.2. Persistence and degradability</u></b>	
<b>Persistence</b>	Insoluble in water.
<b>Degradation in sewage treatment plant</b>	Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.
<b><u>12.3. Bioaccumulative potential</u></b>	May have some potential to bioaccumulate
<b><u>12.4. Mobility in soil</u></b>	Spillage unlikely to penetrate soil Is not likely mobile in the environment due its low water solubility.
<b><u>12.5. Results of PBT and vPvB assessment</u></b>	No data available for assessment.
<b><u>12.6. Other adverse effects</u></b>	
<b>Endocrine Disruptor Information</b>	This product does not contain any known or suspected endocrine disruptors
<b>Persistent Organic Pollutant</b>	This product does not contain any known or suspected substance
<b>Ozone Depletion Potential</b>	This product does not contain any known or suspected substance

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

<b>Waste from Residues / Unused Products</b>	Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.
<b>Contaminated Packaging</b>	Dispose of this container to hazardous or special waste collection point.
<b>European Waste Catalogue (EWC)</b>	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
<b>Other Information</b>	Do not dispose of waste into sewer. Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. Do not let this chemical enter the environment.

## SECTION 14: TRANSPORT INFORMATION

**IMDG/IMO** Not regulated

**14.1. UN number**

**14.2. UN proper shipping name**

**14.3. Transport hazard class(es)**

**14.4. Packing group**

**ADR** Not regulated

**14.1. UN number**

**14.2. UN proper shipping name**

**14.3. Transport hazard class(es)**

**14.4. Packing group**

**IATA** Not regulated

**14.1. UN number**

**14.2. UN proper shipping name**

**14.3. Transport hazard class(es)**

**14.4. Packing group**

**14.5. Environmental hazards** No hazards identified

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

**14.6. Special precautions for user** No special precautions required

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable, packaged goods

## SECTION 15: REGULATORY INFORMATION

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

**International Inventories** X = listed

#### National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.  
Take note of Dir 94/33/EC on the protection of young people at work  
Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work  
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

### Full Text of H-/EUH-Statements Referred to Under Section 3

H360Df - May damage the unborn child. Suspected of damaging fertility  
H412 - Harmful to aquatic life with long lasting effects

#### Legend

**CAS** - Chemical Abstracts Service

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

#### Key literature references and sources for data

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**ENCS** - Japanese Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**PNEC** - Predicted No Effect Concentration

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - Volatile Organic Compounds

#### Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit

# SAFETY DATA SHEET

Dutasteride

Revision Date 18-Apr-2016

and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Creation Date 18-Apr-2016

Revision Date 18-Apr-2016

Revision Summary Not applicable.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

## Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**