

## SAFETY DATA SHEET



### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Material** AVODART SOFT GELATIN CAPSULES

**Synonym(s)** AVODART SOFT GELATIN CAPSULES 0.5 MG \* GI198745X SOFT GELATIN CAPSULES \*  
PRODUCT CODE GX CE2 \* NDC NO 0173-0712-04 \* NDC NO 0173-0712-15 \* DUTASTERIDE,  
FORMULATED PRODUCT

**Company Name**

GlaxoSmithKline, Corporate Environment, Health & Safety  
980 Great West Road  
Brentford, Middlesex TW8 9GS UK

UK General Information: +44-20-8047-5000  
Transport Emergency (EU) +44-1865-407333  
Medical Emergency +1-612-221-3999, Ext 221  
Information and Advice: US number, available 24 hours  
Multi-language response

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249

Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)

Transport Emergency (non EU) +1 703 527 3887 (US)  
available 24 hrs/7 days; multi-language response

Medical Emergency +1 612 221 3999, Ext 221 (US)  
available 24 hrs/7 days; multi-language response

US General Information: +1-888-825-5249  
Transport Emergency (non EU) +1-703-527-3887  
US number, available 24 hours  
Multi-language response

### \* 2. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

Expected to be non-combustible.

**Health**

Exposure might occur via ingestion; skin; eyes.  
Contains one or more components, categorised as potentially harmful to the development of unborn offspring. May produce adverse effects on human fertility. Pharmacological effects may occur following skin absorption.  
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching)  
Health effects information is based on hazards of components.

**Environment**

May cause long-term adverse effects in the aquatic environment. This material may have reproductive or developmental effects on environmental organisms.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
DUTASTERIDE	164656-23-9	0.14	

NON-HAZARDOUS INGREDIENTS Unassigned 99.86

#### 4. FIRST-AID MEASURES

<b>Ingestion</b>	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of soap and water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
<b>Eye contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

#### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Medical treatment in cases of overexposure should be treated as an overdose of a 5-alpha reductase inhibitor. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Health Surveillance Procedures</b>	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
<b>Antidotes</b>	No specific antidotes are recommended.

#### 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	Detergent solutions can be used for clean-up and decontamination operations.

#### 7. HANDLING AND STORAGE

##### HANDLING

**General Requirements** No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

##### STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

## \* 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## OCCUPATIONAL EXPOSURE LIMITS

<b>INGREDIENT</b>	DUTASTERIDE	
<b>GSK Occupational Hazard Category</b>	5	
<b>GSK Occupational Exposure Limit</b>	0.3 mcg/m <sup>3</sup> (8 HR TWA) 3 mcg/m <sup>3</sup> (Short Term Excursion)	REPRODUCTIVE HAZARD, SKIN

## ENGINEERING CONTROLS

<b>Exposure Controls</b>	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. Special considerations apply in the planning, design, review and implementation of controls - seek specialist assistance from local occupational hygienist or safety department.
<b>Containment</b>	Select containment practices which prevent the spread of this material and resulting contamination of surfaces.
<b>Administrative</b>	Only authorised personnel may enter the working area. New or expectant mothers are at greater risk if exposed to the active ingredient which is readily absorbed through the skin. They should not handle unpackaged product. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

## PERSONAL PROTECTIVE EQUIPMENT

<b>Eye Protection</b>	Wear approved safety glasses with side shields or cover goggles if eye contact is possible.
<b>Gloves</b>	Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Glove selection must take into account any solvents and other hazards present. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.
<b>Respirators</b>	Follow local regulations for respirator use in the workplace.
<b>Other Equipment or Procedures</b>	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

## Appearance

<b>Clarity</b>	Opaque.
<b>Colour</b>	Light yellow.
<b>Physical Form</b>	Soft capsule containing liquid.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## \* 11. TOXICOLOGY INFORMATION

<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: a 5-alpha reductase inhibitor.
<b>Target Organ Effects</b>	Adverse effects might occur in the following organ(s) following overexposure: male accessory sex glands; the developing foetus.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Inhalation Toxicity</b>	Substance likely to cause pharmacologically mediated or other adverse effects upon inhalation.

**Material** AVODART SOFT GELATIN CAPSULES

<b>Skin Effects</b>	Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.
<b>Eye Effects</b>	Irritation is not expected following direct contact with eyes.
<b>Sensitisation</b>	Unlikely to be a strong sensitiser in humans. Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Symptoms of hypersensitivity may include skin rash, hives and itching.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	Contains components which have been classified as: Known or presumed to cause toxicity in developing human offspring.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

**Summary** This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. This material contains an active ingredient that may bioaccumulate in the environment. This material contains an active ingredient that may persist in the environment. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active ingredient is provided below.

**ECOTOXICITY****Aquatic****Activated Sludge Respiration**

This material contains an active ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1000 mg/l, 3 Hours, Activated sludge

**Daphnid**

No toxicity to daphnids was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of this compound.

EC50: > 10 mg/l, 48 Hours, Daphnia magna

NOEC: > 10 mg/l, 48 Hours, Daphnia magna

**Fish**

This material contains an active ingredient that is toxic to fish.

Growth Test LOEC: 79 mcg/l, 101 Days, Juvenile Pimephales promelas, fathead minnow, Flow-through test

Growth Test NOEC: 21 mcg/l, 101 Days

**Terrestrial****Earthworm**

This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms.

EC50: 1010 mg/kg, 28 Days, Eisenia foetida, manure worm,

NOEC: 1010 mg/kg, 28 Days, Eisenia foetida, manure worm,

**MOBILITY****Solubility**

This material contains an active ingredient that for environmental fate predictions has limited solubility in water.

**Volatility**

This material contains an active ingredient that will not readily enter into air from water. This material contains an active ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

Henrys Law Constant 6.00E-12 atm m<sup>3</sup>/mol, Calculated at 25 C

**Adsorption**

This material contains an active ingredient that is likely to adsorb to soil or sediment. The active ingredient may persist in soil or sediment if this mixture is released directly to the environment.

**Partitioning**

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

**PERSISTENCE/DEGRADATION**

<b>Hydrolysis</b>	This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.
<b>Photolysis</b>	This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation. UV/Visible Spectrum: 300 at pH 2 to 11
<b>Biodegradation</b>	This material contains an active ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). Aerobic - Ready Percent Degradation: < 1 %, 28 days, Modified Sturm test. Anaerobic Percent Degradation: 12 %, 56 days Aerobic - Soil Percent Degradation: < 2.3 %, 64 days

**BIOACCUMULATION**

<b>Bioaccumulation</b>	This material contains an active ingredient that will have a tendency to bioaccumulate in the food chain.
------------------------	---

## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. The recommended method of disposal is incineration. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this product.

## \* 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification and Labelling**

<b>Transport Information</b>	Not regulated in transport. Store at 25 degrees C (77 degrees F); excursions permitted to 15-30 degrees C (59-86 degrees F).
------------------------------	--

## 15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

**US OSHA Standard (29 CFR Part 1910.1200)**

<b>Classification</b>	This product is classified as hazardous according to the OSHA Hazard Communication Standard. However, products that are subject to the labelling requirements of the Food and Drug Administration are exempt from the labelling provisions of the standard.
-----------------------	---

**Other US Regulations**

<b>TSCA Status</b>	Exempt
--------------------	--------

## 16. OTHER INFORMATION

<b>References</b>	GSK Hazard Determination
<b>SDS Version Number</b>	20

**SDS Sections Updated****Sections**

EXPOSURE CONTROLS / PERSONAL PROTECTION

HAZARDS IDENTIFICATION

TOXICOLOGY INFORMATION

TRANSPORT INFORMATION

**Subsections**

Administrative

Containment

Exposure Controls

Eye Protection

Other Equipment or Procedures

Respirators

Ventilation

Health

Target Organ Effects

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.