



SAFETY DATA SHEET

1. Identification

Product identifier AVODART SOFT GELATIN CAPSULES
Other means of identification Not available.
Synonym(s) AVODART SOFT GELATIN CAPSULES 0.5 MG * GI198745X SOFT GELATIN CAPSULES *
PRODUCT CODE GX CE2 * DUTASTERIDE, FORMULATED PRODUCT
Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

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
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
DUTASTERIDE	GI198745X 4A, 6A, 8-TRIMETHYL-2-OXO-2, 4A, 4B, 5, 6, 6A, 7, 8, 9, 9A, 10, 11, 11A-TETRADECAHYDRO-1H-INDENO(5,4-F ACID(2,5-BIS-TRIFLUOROMETHYLPHENYL 5-ARI GG745 1243 (GW ACN)	164656-23-9	<1.0

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
2,6-DI-TERT-BUTYL-P-CRESOL	BUTYLATED HYDROXYTOLUENE 4-METHYL-2,6-DI-TERT-BUTYLPHENOL BUTYLHYDROXYTOLUENE DIBUTYLATED HYDROXYTOLUENE 2,6-DI-TERT-BUTYL-1-HYDROXY-4-METHY 3,5-DI-TERT-BUTYL-4-HYDROXYTOLUENE 2,6-BIS(1,1-DIMETHYLETHYL)-4-METHYLP 2,6-DI-TERT-BUTYL-4-METHYLPHENOL 2,6-TERT-BUTYL-4-METHYLPHENOL DI-TERT-BUTYLMETHYLPHENOL 2,6-DI-TERT-BUTYL-PARA-CRESOL BHT DBPC DBPD DBMP C15H24O OHS28890 RTECS GO7875000	128-37-0	<0.1
Other components below reportable levels			>99.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: decrease in ejaculatory volume; mild reduction in sperm count; breast enlargement and tenderness in males; decrease in libido; symptoms of hypersensitivity (such as skin rash, hives, itching).
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	In the event of fire, cool tanks with water spray.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
DUTASTERIDE (CAS 164656-23-9)	8 HR TWA	0.3 mcg/m3	
	OHC	5	SKIN REPRODUCTIVE HAZARD
	Short Term Excursion	5	
		3 mcg/m3	
US. ACGIH Threshold Limit Values Components	Type	Value	Form
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)	TWA	2 mg/m3	Inhalable fraction and vapor.
US. NIOSH: Pocket Guide to Chemical Hazards Components	Type	Value	
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)	TWA	10 mg/m3	

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

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. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Hand protection

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other

Not normally needed.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. New or expectant mothers might be at greater risk from overexposure. 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.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Capsule.

Color

Not available.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use. May damage the unborn child by ingestion.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use. Pharmacological effects may occur following skin absorption.
Eye contact	Health injuries are not known or expected under normal use. Avoid contact with eyes.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: decrease in ejaculatory volume; mild reduction in sperm count; breast enlargement and tenderness in males; decrease in libido; symptoms of hypersensitivity (such as skin rash, hives, itching).

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)		
Acute		
<i>Oral</i>		
LD50	Rat	890 mg/kg
DUTASTERIDE (CAS 164656-23-9)		
Acute		
<i>Dermal</i>		
MLD	Rabbit	> 2000 mg/kg

Components	Species	Test Results
Oral MLD	Mouse	> 2000 mg/kg
	Rat	> 1500 mg/kg
Subacute Oral NOAEL	Rat	< 2 mg/kg, 30 days, female 2 mg/kg, 30 days, male

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Irritation Corrosion - Skin DUTASTERIDE		Acute dermal irritation, Primary dermal irritation index = 0.1 Result: Slightly irritating Species: Rabbit
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use.	
Eye DUTASTERIDE		Acute ocular irritation Result: Slight to moderate conjunctival irritation; some iridial involvement Species: Rabbit
Respiratory sensitization	Not available.	
Skin sensitization	Health injuries are not known or expected under normal use.	
Sensitization DUTASTERIDE		Buehler assay Result: Negative Species: Guinea pig
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
DUTASTERIDE		Ames Assay, GLP assay Result: Negative Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative Micronucleus Test, Maximum dose = 1500 mg/kg Result: Negative Species: Rat
Carcinogenicity DUTASTERIDE	Health injuries are not known or expected under normal use.	
		2 year bioassay Result: Negative Species: Mouse 2 year bioassay, Female Result: Negative Species: Rat 2 year bioassay, Male Result: Increase in benign testicular interstitial cell tumours; high dose only (equivalent of 158X human therapeutic dose) Species: Rat
IARC Monographs. Overall Evaluation of Carcinogenicity 2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)	3 Not classifiable as to carcinogenicity to humans.	
Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.	
DUTASTERIDE		Embryo-foetal development - Oral Result: Evidence of feminisation of male foetuses with 0.05 mg/kg/day or more; maternal and foetal toxicity with 2.5 mg/kg/day or more Species: Rat Embryo-foetal development - Oral Result: No maternal toxicity with doses <= 200 mg/kg/day; evidence of feminisation of male foetuses with doses >= 0.05 mg/kg/day Species: Rabbit

DUTASTERIDE

Female Fertility / Early Embryonic Development
 Result: Maternal and foetal toxicity (increased foetal resorptions, decreased foetal weight, feminisation of male foetuses) with doses of 2.5 mg/kg/day or more
 Species: Rat
 Fertility, Male
 Result: Decreased fertility with doses of 0.05 mg/kg/day for up to 31weeks
 Species: Rat
 Pre- and Post-natal development
 Result: Maternal toxicity (reduced weight and lengthened gestation) at 2.5 mg/kg/day or more; no toxic effect dose in male offspring (feminisation) <0.05 mg/kg/day; no toxic effect dose in female offspring = 0.05 mg/kg/day with adverse effects at 2.5 mg/kg/day or
 Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test Results
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	1.44 mg/l, 48 hours, Static test
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	5.3 mg/l, 48 hours, Static test
DUTASTERIDE (CAS 164656-23-9)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 1 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	> 1 mg/l, 48 hours
<i>Chronic</i>			
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	0.079 mg/l, 101 days, Flow-through test, extended OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.021 mg/l, 101 days
Terrestrial			
<i>Acute</i>			
Earthworm	EC50	Manure worm (Eisenia foetida)	1010 mg/kg, 28 days
	NOEC	Manure worm (Eisenia foetida)	1010 mg/kg, 28 days

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

DUTASTERIDE 300, pH 2-11

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

DUTASTERIDE < 2.3 %, 64 days

Percent degradation (Anaerobic biodegradation)

DUTASTERIDE 12 %, 56 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DUTASTERIDE 3.87

Bioconcentration factor (BCF)

2,6-DI-TERT-BUTYL-P-CRESOL 230 - 2500 Measured, Cyprinus carpio, carp

Mobility in soil Not available.**Mobility in general****Volatility****Henry's law**

2,6-DI-TERT-BUTYL-P-CRESOL 0.000004, 25 Estimated

DUTASTERIDE 0 atm m³/mol Calculated, 25 C**Other adverse effects** Not available.**13. Disposal considerations****Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.**Local disposal regulations** Dispose in accordance with all applicable regulations.**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.**14. Transport information****DOT**

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.**15. Regulatory information****US federal regulations****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories** Immediate Hazard - Yes

Delayed Hazard - Yes

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

SARA 302 Extremely hazardous substance No**SARA 311/312 Hazardous chemical** No**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-24-2013

Revision date 10-24-2013

Version # 21

Further information This material has not been assessed for HMIS or NFPA ratings.

References GSK Hazard Determination

Disclaimer 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.

Revision Information Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Toxicological Information:
Ecological Information:
Transport Information:
Regulatory Information: United States
GHS: Classification