

CERTIFICATE FOR SAFETY DATA SHEET
Name of the product: Dutasteride Capsules [0.5mg] [SGC] [US]

Product Code: 2002988

SDS Number: SDS/D1-041-00

Activity	Department	Name	Sign & Date
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RD/FD/009/F-02/RO

Safety data Sheet			
Company Name:		Strides Shasun Ltd	SDS Number: SDS/D1-041-00
Section 1: Identification			
Product Identifier			
Product name:		Dutasteride Capsules [0.5mg] [SGC] [US]	
Trade name:		Not applicable	
Product Code No.:		2002988	
Relevant identified use of the substance or mixture and use advised against			
Recommended Use:		Medicinal Product	
Restrictions on Use:		No other uses are advised.	
Details of the supplier of the safety data sheet:			
Manufacturer name:		Strides Shasun Limited	
Address:		Strides Shasun Limited No 36/7, Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bengaluru, Karnataka, India. 562106	
Telephone Number- General:		91 8067 840307/309	
Emergency Telephone Number:		91 8067 840307/309	
<i>Note: This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).</i>			
Section 2: Hazard Identification:			
Hazard Classification of chemical mixture		Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.	
Signal word		Not applicable	
Hazard statement		Not applicable	
Label elements		Not applicable	
Precautionary statements		Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device. Occupational exposure to the substance or mixture may cause adverse effects.	
Prevention		Not applicable	
Response		Not applicable	
Storage /Disposal EU classification US GHS Classification		Store at (25°C (77°F)); Excursions permitted to 15 – 30°C (59 – 86°F). Dispose in accordance with all applicable regulations	
Section 3: Composition/Information on Ingredients			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Dutasteride USP	164656-23-9	0.5mg	Toxic Repro. 1B: H360 Aquatic (C)3: H412

Mono Diglycerides (Capmul MCM)	26402-22-2	*	Not Listed
Butylated Hydroxytoluene (BHT)	128-37-0	*	Not Listed
Gelatin	9000-70-8	*	232-554-6
Glycerol/Glycerin	56-81-5	*	Not Listed
Glycine	56-40-6	*	Not Listed
Citric Acid, Anhydrous	77-92-9	*	Not Listed
Titanium Dioxide	13463-67-7	*	Not Listed
Ferric oxide (Yellow)	1309-33-7	*	Not Listed
Purified water	7732-18-5	*	231-791-2
Opacode WB Red [NSP-78-15099]	Not applicable	*	Not Listed
Medium chain Triglyceride	73398-61-5	*	Not Listed
Isopropyl Alcohol	67-63-0	*	200-661-7
* Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
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.			
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 and effects both acute and delayed:			
Symptoms	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).		
Other hazards	Not applicable		
UN GHS/ EU EINECS			
Effects:	Not applicable		
Indication of immediate medical attention and special treatment needed			
Notes for the doctor	Not applicable		

Special treatment	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.
Other information	Not applicable
Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media	Water fog, Foam, Dry chemical powder, Carbon dioxide (CO ₂)
Unsuitable Extinguishing Media	None known.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Firefighting Procedures	Use water spray to cool unopened containers.
Un usual fire and Explosion Hazards	No unusual fire or explosion hazards noted.
Hazardous combustion products	During fire, gases hazardous to health may be formed
Advice to fire-fighters	Use standard firefighting procedures and consider the hazards of other involved materials.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	
Personal Precautions:	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Emergency procedures:	No data available
Methods and material for containment and cleaning up	
Containment/Cleanup measures	Collect spillage. Prevent product from entering drains. Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Prohibited materials	Not applicable
Section 7: Handling and Storage	
Precautions for safe handling	
Protective measures:	
Safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Pregnant or breastfeeding women must not handle this product. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Fire Prevention	Not applicable

Dust generation Preventions	Not applicable		
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.		
Conditions for safe storage, including any incompatibilities	Store locked up. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).		
Technical measures and Storage Conditions:	Store at (25°C (77°F)); excursions permitted to 15 – 30°C (59 – 86°F)		
Special Packaging Materials	Not applicable		
Requirement for storage rooms and assembly: Not applicable			
Incompatible materials or ignition sources: Not available			
Section 8: Exposure Controls and personal protection			
Control parameters:			
Exposure Limits/Guidelines: Not available			
Component Name	Result	OSHA	Other agency Information
Dutasteride USP	TWA	0.3 mcg/m ³	No data available
Mono Diglycerides (Capmul MCM)	TWA	No data available	No data available
Butylated Hydroxytoluene (BHT)	TWA	2 mg/m ³	10mg/m ³
Gelatin	TWA	No data available	No data available
Glycerol/Glycerin	TWA	10mg/m ³	5 mg/m ³
Glycine	TWA	No data available	No data available
Citric Acid, Anhydrous	TWA	No data available	No data available
Titanium Dioxide	TWA	15mg/m ³	10mg/m ³
Ferric oxide (Yellow)	TWA	No data available	No data available
Purified water	TWA	No data available	No data available
Opacode WB Red [NSP-78-15099]	TWA	No data available	No data available
Medium chain Triglyceride	PEL/TWA	No data available	No data available
Isopropyl Alcohol	TWA	400 ppm	200 ppm, 400 ppm
Biological limit values: No biological exposure limits noted for the ingredient(s).			
Exposure Controls			
Engineering Controls	General ventilation normally adequate.		
Personal protective equipment			
Hands Protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.		
Eyes Protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.		
Skin Protection	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.		

Respiratory Protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.		
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.		
Special requirements for PPE	Not Applicable		
General hygiene considerations	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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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.		
Section 9: Physical and Chemical properties			
Information on physical and chemical Properties			
Material Description:	Yellow to pale yellow coloured, oblong shaped soft gelatin capsules containing clear oily liquid, imprinted with '0.5'.		
Physical Form:	Soft Gelatin Capsule		
Color:	Yellow to pale yellow		
Odour:	Not Available		
General Properties:			
Boiling point	Not available	Melting point	Not available
Water solubility	Not available	Solvent solubility:	Not available
Specific gravity / Relative density	Not available	pH	Not available
Decomposition temperature	Not available	Viscosity	Not available
Density	Not available	Partition coefficient	Not available
Volatility & Flammability:			
Vapor pressure	Not relevant	Vapor density	Not relevant
Evaporation rate	Not available	UEL (Upper Exposure limit)	Not available
Flash Point	Not available	LEL (Lower Exposure limit)	Not available
Flammability (solid, gas)	Not available	Autoignition Temperature (Solid) (°C)	Not available
Decomposition temperature	Not available.		
Section 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.		

Any stabilizer requirement on storage	Not required	
Conditions to avoid	Contact with incompatible materials.	
Incompatible materials	Strong oxidizing agents, Fluorine.	
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.	
Section 11: Toxicological information		
Information on toxicological effects		
General Information: The information included in this section describes the potential hazards of the individual ingredients.		
Components	CAS No	Acute toxicity
Dutasteride USP	164656-23-9	MLD Oral Mouse >2000 mg/kg MLD Oral Rat >1500 mg/kg
Mono Diglycerides (Capmul MCM)	26402-22-2	LD50 oral rat >5,000 mg/kg, LC50 inhalation rat >20 mg/L
Butylated Hydroxytoluene (BHT)	128-37-0	LD50 Oral Rat >890 mg/kg
Gelatin	9000-70-8	LD50 Oral Rat >3750 mg/kg LD50 Dermal Rabbit > 3600mg/kg
Glycerol/Glycerin	56-81-5	LD 50-12600mg/kg
Glycine	56-40-6	LD50 Oral Rat >7930 mg/kg LD50 Oral Mouse >4920 mg/kg
Citric Acid, Anhydrous	77-92-9	LD50 Oral Rat >3000 mg/kg
Titanium Dioxide	13463-67-7	Not available
Ferric oxide (Yellow)	1309-33-7	LD50 Oral Rat >5000 mg/kg
Purified water	7732-18-5	Not available
Opacode WB Red [NSP-78-15099]	Not available	Not available
Medium chain Triglyceride	73398-61-5	LD60 Oral Rat > 5000mg/kg
Isopropyl Alcohol	67-63-0	LD50 Oral Mouse > 3600mg/kg
Potential Health Effects		
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
Skin contact	Health injuries are not known or expected under normal use.	
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.	
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.	
Acute toxicity	Health injuries are not known or expected under normal use.	
Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Carcinogenicity:	Health injuries are not known or expected under normal use. Due to partial or complete lack of data the classification is not possible.	

Reproductive toxicity:	Components in this product have been shown to -cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.
Aspiration hazard	Not likely, due to the form of the product.
Section 12: Ecological Information:	
Ecotoxicity	Contains a substance which causes risk of hazardous effects to the environment.
Persistence and degradability 1. Photolysis 2. Biodegradability	UV/visible spectrum wavelength; Dutasteride - 300, pH 2-11 Aerobic biodegradation-ready; Dutasteride < 1 %, 28 days Modified Sturm test. Aerobic biodegradation-soil; Dutasteride < 2.3 %, 64 days Anaerobic biodegradation; Dutasteride 12 %, 56 days
Bio accumulative potential 1.Partition coefficient n-octanol/ Water 2.Bioconcentration factor (BCF)	Dutasteride: 3.87 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: 0 atm m ³ /mol Calculated, 25 °C
Other adverse effects	Not Available
Section 13: Disposal Considerations	
Product waste	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.
Packaging waste	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.
Section 14: Transport information	
Not regulated for transport under USDOT, IATA, or IMDG regulations.	
UN Number	Not applicable
UN shipper name	Not applicable
Transport hazard class	Not Dangerous goods
Environmental hazards	Not dangerous goods
DOT	Not regulated as a dangerous good.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.

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.	
Section 15: Regulatory Information		
Safety, Health and environmental regulations/legislation specific for the substance or Mixture		
Components	CAS No	CERCLA/SARA Emission Reporting
Dutasteride USP	164656-23-9	Not Listed
Mono Diglycerides (Capmul MCM)	26402-22-2	Not Listed
Butylated Hydroxytoluene (BHT)	128-37-0	Not Listed
Gelatin	9000-70-8	Not Listed
Glycerol/Glycerin	56-81-5	Not Listed
Glycine	56-40-6	Not Listed
Citric Acid, Anhydrous	77-92-9	Not Listed
Titanium Dioxide	13463-67-7	Not Listed
Ferric oxide (Yellow)	1309-33-7	Not Listed
Purified water	7732-18-5	Not Listed
Opacode WB Red [NSP-78-15099]	Not available	Not Listed
Medium chain Triglyceride	73398-61-5	Not Listed
Isopropyl Alcohol	67-63-0	Not Listed
US federal regulations		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.	
Other federal regulations		
Safe Drinking Water Act	Not regulated.	
US state regulations		
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.	
Section 16: Other information		
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 purpose.		
Reason for revision: (Include Change control number)	New Safety data sheet prepared	
Revision date:	13/06/2018	
Version Number:	00	