# SAFETY DATA SHEET

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

**Material** JALYN CAPSULES 0.5MG/0.4MG

**Synonym(s)** DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE COMBINATION CAPSULES * 0.5 MG DUTASTERIDE AND 0.4 MG TAMSULOSIN HYDROCHLORIDE CAPSULES * NDC 0173-0809-13 * NDC 0173-0809-61 * NDC 0173-0809-59 * DUTASTERIDE AND TAMSULOSIN HYDROCHLORIDE, FORMULATED PRODUCT

**Recommended Use** Medicinal Product

**Company Name**

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000

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
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EMERGENCY PHONE NUMBERS -

TRANSPORT EMERGENCIES (by country / geographic region):

| | |
|---|---|
| Africa / EU / Israel / Middle East (English / European languages): | +44 (0) 1235 239 670 |
| Asia Pacific (except China): | +65 3158 1074 |
| China: | +86 10 5100 3039 |
| Middle East / Africa (Arabic-speaking countries): | +44 (0) 1235 239 671 |
| US: | +1 703 527 3887 |

available 24 hrs/7 days; multi-language response

MEDICAL EMERGENCIES: +1 612 221 3999, Ext 221
available 24 hrs/7 days; multi-language response

## 2. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

Expected to be non-combustible.

**Health** Exposure might occur via skin; eyes.
Caution - Potent pharmaceutical agent.
May produce adverse effects on the development of human 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 | 0.06 | |
| TAMSULOSIN HYDROCHLORIDE | 106463-17-6 | 0.05 | |
| TITANIUM DIOXIDE | 13463-67-7 | 0.3 | 236-675-5 |
| Other components below reportable levels | | >99 | |

## 4. FIRST-AID MEASURES

**Ingestion** 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.

**Inhalation** Physical form suggests that risk of inhalation exposure is negligible.

**Skin contact** 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.

**Eye contact** Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment** 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.

**Medical Conditions Caused or Aggravated by Exposure** None for occupational exposure.

**Health Surveillance Procedures** 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.

**Antidotes** No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

**Fire and Explosion Hazards** Not expected for the product, although the packaging is combustible.

**Extinguishing Media** Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

**Special Firefighting Procedures** 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.

**Hazardous Combustion Products** Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions** Wear protective clothing and equipment consistent with the degree of hazard.

**Environmental Precautions** For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean-up Methods** Collect and place it in a suitable, properly labelled container for recovery or disposal.

**Decontamination Procedures** 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**

| | | |
|---|---|---|
| **INGREDIENT** | DUTASTERIDE | |
| **GSK Occupational Hazard Category** | 5 | |
| **GSK Occupational Exposure Limit** | 0.3 mcg/m3 (8 HR TWA)<br>3 mcg/m3 (Short Term Excursion) | REPRODUCTIVE HAZARD, SKIN |
| **INGREDIENT** | TAMSULOSIN HYDROCHLORIDE | |
| **GSK Occupational Hazard Category** | 4 | |
| **GSK Occupational Exposure Limit** | 3 mcg/m3 (8 HR TWA) | |

**ENGINEERING CONTROLS**

**Exposure Controls** The active ingredient was formerly assigned to OHC 4 with the Highly Potent notation. 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.

**Containment** Open handling may result in overexposure. It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination.

**Ventilation** Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.

**Administrative** Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas.

**PERSONAL PROTECTIVE EQUIPMENT**

**Eye Protection** When isolation is not possible, chemical splash goggles or equivalent eye protection must be used with other applicable protective equipment.

**Gloves** 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.

**Respirators** When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.

**Other Equipment or Procedures** Follow all local regulations if personal protective equipment (PPE) is used in the workplace. When isolation is not possible in production areas, applicable protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

## * 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

**Physical Form** Capsule.

## 10. STABILITY AND REACTIVITY

**Stability** This product is expected to be stable.

**Conditions to Avoid** None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

**Pharmacological Effects** This product contains active ingredient(s) with the following activity: a 5-alpha reductase inhibitor; an anti-adrenergic agent.

**Target Organ Effects** Adverse effects might occur in the following organ(s) following overexposure: male accessory sex glands.

**Routes of Exposure**

**Oral Toxicity** Not expected to be toxic following ingestion.

**Inhalation Toxicity** Substance likely to cause pharmacologically mediated or other adverse effects upon inhalation.

**Skin Effects** Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.

**Eye Effects** Irritation is not expected following direct contact with eyes.

**Sensitisation** 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.

**Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions.

**Carcinogenicity** Not expected to produce cancer in humans under occupational exposure conditions. Contains a material classified as a carcinogen by external agencies. (IARC) Animal carcinogen. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

**Reproductive Effects** Contains components which have been classified as: Known or presumed to cause toxicity in developing human offspring.

**Other Adverse Effects** 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 m3/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**

**Hydrolysis** 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.

**Photolysis** This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation.

UV/Visible Spectrum: 300 at pH 2 to 11

**Biodegradation** 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**

**Bioaccumulation** This material contains an active ingredient that will have a tendency to bioaccumulate in the food chain.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Recommendations** 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.

**Regulatory Requirements** 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**

**Transport Information** Not regulated in transport.

## 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)**

**Classification** Exempt when packaged for sale to consumers in a retail establishment.

**Other US Regulations**

**TSCA Status** Exempt

## 16. OTHER INFORMATION

**References** GSK Hazard Determination

**SDS Version Number** 5

### SDS Sections Updated

| Sections | Subsections |
|---|---|
| PHYSICAL AND CHEMICAL PROPERTIES | |

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.