

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	ANDROPATCH
Synonyms	ANDROPATCH 2.5 MG * ANDROPATCH 5 MG * TESTOSTERONE, 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, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
TESTOSTERONE	58-22-0	5
ETHANOL	64-17-5	40 to 50
NON-HAZARDOUS INGREDIENTS	Unassigned	45 to 55

3. HAZARDS IDENTIFICATION

Fire and Explosion	Assume that this product is capable of sustaining combustion.
Health	Caution - Potent pharmaceutical agent. Pharmacological effects may occur following skin absorption. Exposure might occur via skin; eyes. Health effects information is based on hazards of components. Handling this product in its final form presents minimal risk from occupational exposure.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

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 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	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
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	The combustibility of the product is not known, however the packaging is combustible.
Extinguishing Media	Water or foam extinguishers are recommended. Carbon dioxide or dry powder 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	No specific decontamination or detoxification procedures have been identified for this product.

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 The recommended temperature for storage is less than 40 °C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT TESTOSTERONE

GSK Occupational Hazard Category 4

GSK Occupational Exposure Limit 4 mcg/m³ (8 HR TWA) CARCINOGEN, REPRODUCTIVE HAZARD, SKIN

ENGINEERING CONTROLS

Exposure 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.

Administrative 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.

Other Equipment or Procedures Wash hands and arms thoroughly after handling. None required for normal handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity Clear.

Physical Form Laminate patch.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Not expected to be toxic following ingestion.

* **Inhalation Toxicity** Inhalation toxicity is not expected.

* **Skin Effects** Not expected to be a significant skin irritant. Assessment based upon extensive use or exposure in humans. May be absorbed through the skin. Pharmacological effects may occur following skin absorption.

Eye Effects Not applicable for this product.

* **Target Organ Effects** Adverse effects might occur in the following organ(s) following overexposure: liver; adrenal glands; testes; ovary.

* **Sensitisation** Sensitisation (allergic skin reaction) is not expected. Assessment based upon information from human exposure.

* **Genetic Toxicity** Not expected to be genotoxic based on examination of the chemical structure and effects of similar materials.

- * **Carcinogenicity** Testosterone, the active substance in this product, produced carcinogenic effects in a lifetime study in mice.
Possible human carcinogen.
Classification by external agencies: (IARC) Animal carcinogen.
However, the relevance of these effects to humans from occupational exposure is not known.
- * **Reproductive Effects** Contains components which have been classified as:
Known or presumed to impair fertility in humans.
Known or presumed to cause toxicity in developing human offspring.
Known or presumed to affect the quantity and quality of breast milk in humans.
- * **Pharmacological Effects** This product contains active ingredient(s) with the following activity: an androgenic, anabolic steroid.
- * **Other Adverse Effects** This material is a steroid that might produce effects similar to male reproductive hormones.

12. ECOLOGICAL INFORMATION

- Summary** No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

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.
- 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** Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

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** This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

- TSCA Status** Exempt

16. OTHER INFORMATION

- References** GSK Hazard Determination

Date Approved/Revised 15-Mar-2007

SDS Version Number 11

SDS Sections Updated**Sections**

HAZARDS IDENTIFICATION
REGULATORY INFORMATION
TOXICOLOGY INFORMATION

Subsections

Health
US Environmental (EPA) Requirements
Carcinogenicity
Eye Effects
Genetic Toxicity
Inhalation Toxicity
Oral Toxicity
Other Adverse Effects
Pharmacological Effects
Reproductive Effects
Sensitisation
Skin Toxicity
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.