

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>TEMOVATE SCALP APPLICATION</b>
<b>Synonym(s)</b>	TEMOVATE SCALP APPLICATION 0.05% * DERMOVATE SCALP APPLICATION 0.05% * DERMOXINALE LOTION 0.05% * PSOREX SCALP APPLICATION 0.05% * NDC NO 59075-432-00 * NDC NO 59075-432-01 * CLOBETASOL PROPIONATE, FORMULATED PRODUCT
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>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</p> <p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
CLOBETASOL PROPIONATE	25122-46-7	0.05	
ISOPROPYL ALCOHOL	67-63-0	39.26	200-661-7
NON-HAZARDOUS INGREDIENTS	Unassigned	60.69	

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	This product is classified as flammable.
<b>Health</b>	<p>Caution - Potent pharmaceutical agent. Health effects information is based on hazards of components. May cause steroid withdrawal rash. Possible effects of overexposure in the workplace include: symptoms similar to alcohol intoxication.</p>
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

## 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 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>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
<b>Antidotes</b>	No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	This product is flammable. Fire and explosions might result if vapours are allowed to accumulate in the vicinity of a source of ignition.
<b>Extinguishing Media</b>	Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or 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. Move containers from the fire area if possible without increased personal risk.
<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>	Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.
<b>Environmental Precautions</b>	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
<b>Clean-up Methods</b>	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal. Equipment used for clean-up should be earthed (grounded) and non-sparking.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this product. Detergent solutions can be used for clean-up and decontamination operations.

## 7. HANDLING AND STORAGE

### HANDLING

<b>General Requirements</b>	Ensure that any area in which this material is handled has sufficient ventilation to avoid the build up of vapour and to control employee potential exposure to volatiles below National Occupational Exposure Limits.
<b>Ignition Controls</b>	Keep this material away from all forms of ignition such as open flames, mechanical sparks, frictional heat and hot surfaces.

Material TEMOVATE SCALP APPLICATION

**STORAGE** Keep material in sealed containers in a cool, well-ventilated area away from sources of ignition.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>INGREDIENT</b>	CLOBETASOL PROPIONATE	
<b>GSK Occupational Hazard Category</b>	4	
<b>GSK Occupational Exposure Limit</b>	2 mcg/m <sup>3</sup> (8 HR TWA)	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.

### PERSONAL PROTECTIVE EQUIPMENT

<b>Eye Protection</b>	Wear approved safety glasses with side shields if eye contact is possible.
<b>Other Equipment or Procedures</b>	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

<b>Physical Form</b>	Solution.
<b>Flash Point</b>	19.4 °C (Closed Cup).
<b>pH of Aqueous Solutions</b>	5.5 to 5.8

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	Avoid direct sunlight, conditions that might generate heat and sources of ignition.

## 11. TOXICOLOGY INFORMATION

<b>Pharmacological Effects</b>	This material is a selective glucocorticoid receptor agonist. Adverse effects of overexposure might include: suppression of adrenal glands; temporary decrease in white blood cell counts; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); increased susceptibility to infection.
<b>Target Organ Effects</b>	Adverse effects might occur in the following organ(s) following overexposure: adrenal glands; immune system.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Skin Effects</b>	Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.
<b>Eye Effects</b>	Minor irritation might occur following direct contact with eyes.
<b>Sensitisation</b>	Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

**Summary** This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. This material contains an active pharmaceutical ingredient that may persist in the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

### ECOTOXICITY

#### Aquatic

##### Activated Sludge Respiration

This material is not toxic to activated sludge microorganisms.

IC50: > 100 mg/l, 3 Hours, Activated sludge, Nominal

NOEC: 100 mg/l, 3 Hours

##### Algal

This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 4.2 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Measured

NOEC: 1.3 mg/l, 72 Hours

##### 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: > 1.4 mg/l, 48 Hours, Daphnia magna, Measured

NOEC: 1.4 mg/l, 48 Hours

##### Fish

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

Juvenile Oncorhynchus mykiss, rainbow trout

EC50: > 0.75 mg/l, 96 Hours, Measured

NOEC: 0.75 mg/l, 96 Hours

### MOBILITY

#### Solubility

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

#### 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

#### Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

Aerobic - Inherent

Percent Degradation: < 5 %, 14 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

## 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. 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

<b>Technical Name</b>	TEMOVATE SCALP APPLICATION 0.05%
<b>Proper Shipping Name</b>	Isopropyl Alcohol Solution (TEMOVATE SCALP APPLICATION 0.05%)
<b>UN Number</b>	UN 1219
<b>Class/Division</b>	3
<b>Subsidiary Risk</b>	None
<b>Packing Group</b>	II
<b>Risk Label(s)</b>	Class 3 Flammable Liquid



### International Air Transport (IATA Requirements)

**Classification and Labelling** As UN Classification and Labelling above

### International Maritime Transport (IMDG Requirements)

**Classification and Labelling** As UN Classification and Labelling above

### US Domestic Transport (DOT Requirements)

**Classification and Labelling** As UN Classification and Labelling above

### European Ground Transport (ADR/RID Requirements)

**Classification and Labelling** Not regulated according to ADR/RID requirements.

## 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 product is classified as hazardous according to the OSHA Hazard Communication Standard.

### Other US Regulations

**TSCA Status** Exempt

## 16. OTHER INFORMATION

**References** GSK Hazard Determination

**SDS Version Number** 13

### SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	

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.