

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	TEMOVATE OINTMENT
Synonym(s)	TEMOVATE OINTMENT , 0.05% * DERMOVATE OINTMENT, 0.05% * DERMOVATE MASC * DERMOVATE MAST * DERMOVATE MERHEM * DERMOVATE OLDAT * DERMOVATE ONGUENT * DERMOVATE POMADA * DERMOVATE SALBE * DERMOVATE UNGUENT * DERMOVATE UNGUENTO * DERMOVATE ZIEDE * PSOREX OINTMENT * DERMOXIN SALBE * CLOBETASOL PROPIONATE, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & 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 & 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	
Other components below reportable levels		>99	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	Caution - Potent pharmaceutical agent. Health effects information is based on hazards of components. May cause steroid withdrawal rash.
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.

Material TEMOVATE OINTMENT

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 treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid.
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.
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 is recommended for fires involving packaging.
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

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	CLOBETASOL PROPIONATE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	2 mcg/m ³ (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.	

Material TEMOVATE OINTMENT

PERSONAL PROTECTIVE EQUIPMENT

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

9. PHYSICAL AND CHEMICAL PROPERTIES
--

Appearance

Physical Form	Ointment.
----------------------	-----------

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 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.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: adrenal glands; immune system.
Routes of Exposure	
Oral Toxicity	Not expected to be toxic following ingestion.
Skin Effects	Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.
Eye Effects	Minor irritation might occur following direct contact with eyes.
Sensitisation	Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Other Adverse Effects	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

Material TEMOVATE OINTMENT

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.

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.

For waste disposal purpose, this product should be classified in line with the European Waste Catalogue criteria.

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 9

SDS Sections Updated**Sections****Subsections**

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF
COMPANY

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.