

## SAFETY DATA SHEET



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

<b>Material</b>	DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 1% - 5%)										
<b>Synonym(s)</b>	DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 1%) * DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 2%) * DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 4%) * DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 5%) * DUAC TOPICAL GEL * DUAC GEL * CLINDAMYCIN PHOSPHATE 1% WITH BENZOYL PEROXIDE 1% - 5% * FORMULATION CODES: 516A, 516B, 516C * STIEFEL PRODUCT * CLINDAMYCIN PHOSPHATE AND BENZOYL PEROXIDE, FORMULATED PRODUCT										
<b>Recommended Use</b>	Medicinal Product										
<b>Note</b>	This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.										
<b>Company Name</b>	<p>GlaxoSmithKline UK 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information (normal business hours): +44-20-8047-5000</p> <p>GlaxoSmithKline US 5 Moore Drive Research Triangle Park, NC 27709 USA US General Information (normal business hours): +1-888-825-5249</p> <p>Email Address: <a href="mailto:msds@gsk.com">msds@gsk.com</a> Website: <a href="http://www.gsk.com">www.gsk.com</a></p> <p>EMERGENCY PHONE NUMBERS -</p> <p>TRANSPORT EMERGENCIES (by country / geographic region):</p> <table border="0" style="width: 100%;"> <tr> <td>Africa / EU / Israel / Middle East (English / European languages):</td> <td style="text-align: right;">+44 (0) 1235 239 670</td> </tr> <tr> <td>Asia Pacific (except China):</td> <td style="text-align: right;">+65 3158 1074</td> </tr> <tr> <td>China:</td> <td style="text-align: right;">+86 10 5100 3039</td> </tr> <tr> <td>Middle East / Africa (Arabic-speaking countries):</td> <td style="text-align: right;">+44 (0) 1235 239 671</td> </tr> <tr> <td>US:</td> <td style="text-align: right;">+1 703 527 3887</td> </tr> </table> <p>available 24 hrs/7 days; multi-language response</p> <p>MEDICAL EMERGENCIES: <span style="float: right;">+1 612 221 3999, Ext 221</span> available 24 hrs/7 days; multi-language response</p>	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
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### 2. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

Assume that this product is capable of sustaining combustion.

<b>Health</b>	Caution - Pharmaceutical agent. Not expected to be a significant health hazard unless product is spilt. Health effects information is based on hazards of components. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: irritation; redness; symptoms of hypersensitivity (such as skin rash, hives, itching). Exposure might occur via inhalation; ingestion; skin; eyes.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects. This product contains an ingredient(s) that is very toxic to aquatic organisms; and may cause long-term adverse effects in the aquatic environment. Environmental information on components is listed in Section 12.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
BENZOYL PEROXIDE HYDROUS 75%, USP	Unassigned	1 to 7.5	202-327-6
CLINDAMYCIN PHOSPHATE	24729-96-2	1.0	246-433-0
Other components below reportable levels		> 90	

### 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>	Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.
<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.
<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>	The combustibility of the product is not known, however the packaging is combustible.
<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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

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**6. ACCIDENTAL RELEASE MEASURES**

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<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this product.

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**7. HANDLING AND STORAGE**

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**HANDLING**

<b>General Requirements</b>	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.
<b>Ignition Controls</b>	Avoid contact with ignition sources.
<b>STORAGE</b>	Keep material in sealed containers in a cool, well-ventilated area away from sources of ignition. The recommended temperature for storage is 2 to 8 °C.

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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<b>Other Equipment or Procedures</b>	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
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**9. PHYSICAL AND CHEMICAL PROPERTIES**

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**Appearance**

<b>Colour</b>	White/light yellow.
<b>Physical Form</b>	Gel.
<b>Flash Point</b>	No studies have been conducted.

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**10. STABILITY AND REACTIVITY**

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<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.

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**11. TOXICOLOGY INFORMATION**

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<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: an antibiotic.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Symptoms of Overexposure</b>	Possible effects of overexposure in the workplace include: irritation; redness; symptoms of hypersensitivity (such as skin rash, hives, itching).
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion. Assessment based upon effects of individual components.
<b>Inhalation Toxicity</b>	Inhalation toxicity is not expected. Assessment based upon the physico-chemical properties of this material.
<b>Skin Effects</b>	Minor irritation might occur following direct contact.
<b>Eye Effects</b>	Minor irritation might occur following direct contact with eyes.
<b>Sensitisation</b>	Allergic skin reactions might occur following dermal exposure. Symptoms of hypersensitivity may include skin rash, hives and itching. Assessment based upon effects of individual components.
<b>Genetic Toxicity</b>	Not expected to be genotoxic, based on effects of individual components.
<b>Carcinogenicity</b>	Studies have been conducted and this material is not listed as a carcinogen by GSK, IARC, NTP or US OSHA. 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. Assessment based upon effects of individual components.

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	This material contains an active ingredient (benzoyl peroxide) that has been tested and which may be very toxic to aquatic organisms if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. 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.
<b>ECOTOXICITY</b>	
<b>Aquatic</b>	
<b>Activated Sludge Respiration</b>	This material contains an active ingredient that is harmful to activated sludge microorganisms. IC50: 35 mg/L, 30 Minutes, Activated sludge
<b>Algal</b>	This material contains an active ingredient that is very toxic to algae. IC50: 0.07 mg/L, 72 Hours, Selenastrum capricornutum, green algae, Static test
<b>Daphnid</b>	This material contains an active pharmaceutical ingredient that is very toxic to daphnids. EC50: 0.07 mg/L, 48 Hours, Daphnia magna, Static test
<b>Fish</b>	This material contains an active ingredient that is very toxic to fish. EC50: 0.24 mg/L, 96 Hours, Juvenile Oryzias latipes, orange-red killfish, Flow-through test EC50: 2 mg/L, 96 Hours, Juvenile Poecilia reticulata, guppy
<b>MOBILITY</b>	
<b>Solubility</b>	This material contains an active ingredient that for environmental fate predictions has very low solubility in water.
<b>Volatility</b>	This material contains an active ingredient that will readily enter into air from water. Henry's Law Constant 3.50E-06 atm m <sup>3</sup> /mol, Calculated
<b>Adsorption</b>	This material contains an active ingredient that is likely to adsorb to soil or sediment. Soil Sediment Sorption 3.26, Estimated (log K <sub>oc</sub> ):
<b>Partitioning</b>	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.
<b>PERSISTENCE/DEGRADATION</b>	
<b>Hydrolysis</b>	This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism. Half-Life, Neutral: 5.2 Hours, Measured, pH 7 Buffer Solution Half-Life, Acidic: 11.87 Hours, Measured, pH 4 buffer solution
<b>Photolysis</b>	This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in the atmosphere. Atmospheric photolysis may be a significant depletion mechanism. Half-Life, Atmospheric: 4.5 Days, Estimated
<b>Biodegradation</b>	This material contains an active ingredient that is readily degradable (as defined by Chemicals Hazard Information and Packaging (CHIP) for Supply Regulations 1994 as amended) and is not expected to persist in the environment. Aerobic - Ready Percent Degradation: 83 %, 20 Days, MITI test, Activated sludge
<b>BIOACCUMULATION</b>	
<b>Bioaccumulation</b>	This material contains an active ingredient that will not have a tendency to bioaccumulate in the food chain.
<b>Bioconcentration Factor:</b>	92 Estimated

**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** Per UN Model Regulation 5.2.1.6, may require environmentally hazardous substance mark (fish and tree symbol).

**Technical Name** CLINDAMYCIN PHOSPHATE 1% WITH BENZOYL PEROXIDE 5%

**Proper Shipping Name** Environmentally hazardous substance, liquid, .n.o.s.  
(DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 1- 5%))

**UN Number** UN 3082

**Class/Division** 9

**Packing Group** III

**Risk Label(s)** Class 9



**International Air Transport (IATA Requirements)**

**UN/ID Number** ID 8000

**Proper Shipping Name/Description** Consumer Commodity

**ICAO/IATA Class/Division** 9

**Hazard Label(s)** Class 9



**Packing Instructions** See Packing Instruction Y963.

**Limited Quantities** May be able to ship as an Excepted Quantity.

**International Maritime Transport (IMDG Requirements)**

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

**Limited Quantities** May be able to ship as an Excepted or Limited Quantity.

**US Domestic Transport (DOT Requirements)**

**Proper Shipping Name** Consumer Commodity, ORM-D

**UN/NA Number** None

**Label Code(s)** None

**Classification and Labelling** See 173.155 and 173.156

**European Ground Transport (ADR/RID Requirements)****Classification and Labelling** See SP 601.**Limited Quantities** As packaged for retail sale and distribution, not subject to ADR provisions.

15. REGULATORY INFORMATION
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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
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**References** GSK Hazard Determination**SDS Version Number** 4**SDS Sections Updated****Sections**

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

**Subsections**

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.