SAFETY DATA SHEET

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

Material: DUAC TOPICAL GEL (CLINDAMYCIN 1% - BENZOYL PEROXIDE 1% - 5%)

Synonym(s):
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

Recommended Use:
Medicinal Product

Note:
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.

Company Name:
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Brentford, Middlesex TW8 9GS UK
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5 Moore Drive
Research Triangle Park, NC 27709 USA
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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):
China:
Middle East / Africa (Arabic-speaking countries): +44 (0) 1235 239 671
US:
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
Assume that this product is capable of sustaining combustion.
Health
Caution - Pharmaceutical agent.
Not expected to be a significant health hazard unless product is split.
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.

Environment
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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>Percent</th>
<th>EC-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZOYL PEROXIDE HYDROUS 75%, USP</td>
<td>Unassigned</td>
<td>1 to 7.5</td>
<td>202-327-6</td>
</tr>
<tr>
<td>CLINDAMYCIN PHOSPHATE</td>
<td>24729-96-2</td>
<td>1.0</td>
<td>246-433-0</td>
</tr>
<tr>
<td>Other components below reportable levels</td>
<td>&gt; 90</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
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.

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.

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
Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water
extinguishers. Water jets may intensify the fire or 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.

Ignition Controls
Avoid contact with ignition sources.

STORAGE
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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Other Equipment or Procedures
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour
White/light yellow.

Physical Form
Gel.

Flash Point
No studies have been conducted.

10. STABILITY AND REACTIVITY

Stability
This product is expected to be stable.

Conditions to Avoid
Avoid direct sunlight, conditions that might generate heat and sources of ignition.

11. TOXICOLOGY INFORMATION

Pharmacological Effects
This product contains active ingredient(s) with the following activity: an antibiotic.

Target Organ Effects
No specific target organ effects have been identified.

Symptoms of Overexposure
Possible effects of overexposure in the workplace include: irritation; redness; symptoms of hypersensitivity (such as skin rash, hives, itching).

Routes of Exposure

Oral Toxicity
Not expected to be toxic following ingestion.
Assessment based upon effects of individual components.

Inhalation Toxicity
Inhalation toxicity is not expected. Assessment based upon the physico-chemical properties of this material.

Skin Effects
Minor irritation might occur following direct contact.

Eye Effects
Minor irritation might occur following direct contact with eyes.

Sensitisation
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.

Genetic Toxicity
Not expected to be genotoxic, based on effects of individual components.

Carcinogenicity
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.

Reproductive Effects
Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Assessment based upon effects of individual components.
## 12. ECOLOGICAL INFORMATION

### Summary
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.

### ECOTOXICITY

#### Aquatic

<table>
<thead>
<tr>
<th>Aquatic</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated Sludge</td>
<td>This material contains an active ingredient that is harmful to activated sludge microorganisms.</td>
<td>IC50: 35 mg/L, 30 Minutes, Activated sludge</td>
</tr>
<tr>
<td>Respiration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algal</td>
<td>This material contains an active ingredient that is very toxic to algae.</td>
<td>IC50: 0.07 mg/L, 72 Hours, Selenastrum capricornutum, green algae, Static test</td>
</tr>
<tr>
<td>Daphnid</td>
<td>This material contains an active pharmaceutical ingredient that is very toxic to daphnids.</td>
<td>EC50: 0.07 mg/L, 48 Hours, Daphnia magna, Static test</td>
</tr>
<tr>
<td>Fish</td>
<td>This material contains an active ingredient that is very toxic to fish.</td>
<td>EC50: 0.24 mg/L, 96 Hours, Juvenile Oryzias latipes, orange-red killfish, Flow-through test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EC50: 2 mg/L, 96 Hours, Juvenile Poecilia reticulata, guppy</td>
</tr>
</tbody>
</table>

### MOBILITY

| Solubility | This material contains an active ingredient that for environmental fate predictions has very low solubility in water. |
| Volatility | This material contains an active ingredient that will readily enter into air from water. |
| Henrys Law Constant | 3.50E-06 atm m3/mol, Calculated |
| Adsorption | This material contains an active ingredient that is likely to adsorb to soil or sediment. |
| Soil Sediment Sorption | log Koc: 3.26, Estimated |

### PERSISTENCE/DEGRADATION

| Hydrolysis | 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 |
| Photolysis | 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 |
| Biodegradation | 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 |

### BIOACCUMULATION

| Bioaccumulation | This material contains an active ingredient that will not have a tendency to bioaccumulate in the food chain. |
| Bioconcentration Factor | 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

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.

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  4

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.