

SAFETY DATA SHEET



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

Material	PANOXYL (4% - 8%) ACNE CREAMY WASH										
Synonym(s)	PANOXYL CREAMY WASH (4% BENZOYL PEROXIDE, BPO) * PANOXYL CREAMY WASH (8% BENZOYL PEROXIDE, BPO) * PANOXYL CREAMY WASH (4% - 8% BENZOYL PEROXIDE) * PANOXYL CREAMY WASH 4% * PANOXYL CREAMY WASH 8% * FORMULATION CODES: MF1002; 672A; 673A; 515A * STIEFEL PRODUCT * BENZOYL PEROXIDE, FORMULATED PRODUCT										
Recommended Use	Cosmetic 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	<p>Stiefel Laboratories, Inc. (a GSK company) 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: msds@gsk.com Website: www.gsk.com</p> <p>EMERGENCY PHONE NUMBERS -</p> <p>TRANSPORT EMERGENCIES (by country / geographic region):</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 80%;">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: +1 612 221 3999, Ext 221 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

This product is non-flammable.

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Health	Handling this product in its final form presents minimal risk from occupational exposure. May cause transient eye irritation. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: irritation; symptoms of hypersensitivity (such as skin rash, hives, itching). Health effects information is based on hazards of components. Exposure might occur via ingestion; skin; eyes.
Environment	Dangerous for the environment. Very toxic to aquatic organisms.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
BENZOYL PEROXIDE HYDROUS 75%, USP	Unassigned	5.0 - 12.0	202-327-6
GLYCOLIC ACID	79-14-1	0.55	201-180-5
SODIUM PCA	28874-51-3	2.0	249-277-1
TENSIANOL SOAP BASE		38.0 - 42.0	
Other components below reportable levels		<55.0	

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	In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.
Medical Conditions Caused or Aggravated by Exposure	Ocular symptoms may be indicative of allergic reaction.
Health Surveillance Procedures	The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting skin conditions. In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting skin conditions and other allergy symptoms.
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	No special requirements needed.
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.

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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 are considered necessary for the control of fire and explosion hazards.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection Wear approved safety glasses with side shields if eye contact is possible.

Other Equipment or Procedures An eye wash station should be available. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Cream.

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

Symptoms of Overexposure Possible effects of overexposure in the workplace include: irritation; 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 No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Minor irritation might occur following direct contact with eyes. Assessment based upon effects of individual components.

Sensitisation Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Symptoms of hypersensitivity may include skin rash, hives and itching.

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

Carcinogenicity 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.

12. ECOLOGICAL INFORMATION

Summary	This material contains an active ingredient that has been tested and which may be harmful 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	
Activated Sludge Respiration	This material contains an active ingredient that is harmful to activated sludge microorganisms. IC50: 35 mg/L, 30 Minutes, Activated sludge
Algal	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
Daphnid	This material contains an active pharmaceutical ingredient that is very toxic to daphnids. EC50: 0.07 mg/L, 48 Hours, Daphnia magna, Static test
Fish	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
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. Henry's Law Constant 3.50E-06 atm m ³ /mol, Calculated
Adsorption	This material contains an active ingredient that is likely to adsorb to soil or sediment. Soil Sediment Sorption 3.26, Estimated (log K _{oc}):
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	
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

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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 PANOXYL CREAMY WASH (4% - 8% BENZOYL PEROXIDE)

Proper Shipping Name Environmentally hazardous substance, liquid, .n.o.s.

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.

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International Maritime Transport (IMDG Requirements)

UN Number	UN 3082
Proper Shipping Name/Description	Environmentally hazardous substance, liquid, .n.o.s.
IMO Class/Division	9
Packing Group	III
Class Label(s)	Class 9



Classification and Labelling	See SP 335.
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	Not subject to ADR, see SP 601.
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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	Exempt when packaged for sale to consumers in a retail establishment.
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Other US Regulations

TSCA Status	Exempt
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16. OTHER INFORMATION

References	GSK Hazard Determination
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SDS Version Number	2
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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.