

SAFETY DATA SHEET



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

Material	PANOXYL ACNE CLEANSING BAR (5% - 10% BENZOYL PEROXIDE)
Synonym(s)	PANOXYL 5% ACNE FOAMING BAR * PANOXYL 10% ACNE FOAMING BAR * PANOXYL FOAMING BAR (5% BENZOYL PEROXIDE, BPO) * PANOXYL FOAMING BAR (10% BENZOYL PEROXIDE, BPO) * BENZOYL PEROXIDE ACNE CLEANSING BAR 5 % - 10% * PANOXYL ACNE CLEANSING BAR (CONTAINING 5% - 10% BENZOYL PEROXIDE) * FORMULATION CODES: 103A, 104A * 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): 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 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>

2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

Expected to be non-combustible.

Health

Handling this product in its final form presents minimal risk from occupational exposure.
 May cause transient eye irritation.
 May produce allergic skin reactions.
 Health effects information is based on hazards of components.
 Exposure might occur via ingestion; skin; eyes.

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Environment Dangerous for the environment. Very toxic to aquatic organisms.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
BENZOYL PEROXIDE	94-36-0	5.0 - 10.0	202-327-6
Other components below reportable levels		90.0 - 95.0	

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	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	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.
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.

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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

Other Equipment or Procedures

None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Bar.

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

Target Organ Effects

No specific target organ effects have been identified.

Routes of Exposure**Oral Toxicity**

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

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.

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

No adverse effects have been reported following extensive use or exposure in humans.

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

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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 (log K _{oc}): 3.26, Estimated
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

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 ACNE CLEANSING BAR (CONTAINING 5% - 10% BENZOYL PEROXIDE)
Proper Shipping Name	Environmentally hazardous substance, solid, nos
UN Number	UN 3077
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)

UN Number	UN 3077
Proper Shipping Name/Description	Environmentally hazardous substance, solid, nos
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.

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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.

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.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 2

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.