

SAFETY DATA SHEET



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

Material	BACTROBAN CREAM
Synonyms	BACTROBAN CREAM 2% * NDC NO. 0029-1527-22 * NDC NO. 0029-1527-25 * CALCIUM MUPIROCIN, FORMULATED PRODUCT
Company Name	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK 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 GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
CALCIUM MUPIROCIN DIHYDRATE	115074-43-6	3
NON-HAZARDOUS INGREDIENTS	Unassigned	97

3. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as a non-combustible solid and will not support propagating combustion.
* Health	Caution - Pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. Health effects information is based on hazards of components.
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.
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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	None.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
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	Detergent solutions can be used for clean-up and decontamination operations. 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.
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STORAGE

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT CALCIUM MUPIROCIN DIHYDRATE

GSK Occupational Hazard Category 1

GSK Occupational Exposure Limit 5000 mcg/m³ (8 HR TWA)

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.

Other Equipment or Procedures Wash hands and arms thoroughly after handling. None required for normal handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Cream.

Flash Point 120 °C (Closed Cup).

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Not expected to be toxic following ingestion.

Skin Effects Irritation is not expected following direct contact.

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

Sensitisation Sensitisation (allergic skin reaction) is not expected.

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

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

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary** This material has had limited testing. There is insufficient information to determine the scope of the environmental effects this material may cause. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

* Daphnid	This material contains an active pharmaceutical ingredient that is not toxic to daphnids.
	EC50: > 1000 mg/l, 48 Hours, Daphnia magna, Nominal
	NOEL: 1000 mg/l

MOBILITY

* Solubility	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
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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	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.
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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	This product is classified as hazardous according to the OSHA Hazard Communication Standard.
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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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Date Approved/Revised 02-Mar-2006

SDS Version Number 8

SDS Sections Updated**Sections**

ECOLOGICAL INFORMATION

Subsections

Activated Sludge Respiration
Adsorption
Algal
Algal Degradation
Bioaccumulation
Biodegradation
Daphnid

SDS Sections Updated**Sections**

ECOLOGICAL INFORMATION

HAZARDS IDENTIFICATION

IDENTIFICATION OF SUBSTANCE / PREPARATION AND
OF COMPANY

REGULATORY INFORMATION

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.

Subsections

Distribution

Earthworm

Ecotoxicity

Fish

GSK Environmental Hazard Category

Hydrolysis

Microbial Growth Inhibition

Microtox

Mobility

Other Adverse Effects

Other Species - Aquatic

Other Species - Terrestrial

Partitioning

Persistence/Degradation

Photolysis

Solubility

Summary

Volatility

Health

US Environmental (EPA) Requirements