

## SAFETY DATA SHEET



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

<b>Material</b>	BACTROBAN CREAM												
<b>Synonym(s)</b>	BACTROBAN CREAM 2% * CALCIUM MUPIROCIN, FORMULATED PRODUCT * NDC NO. 0029-1527-22 * NDC NO. 0029-1527-25												
<b>Recommended Use</b>	Medicinal Product												
<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 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 3101 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;">+961 3 487 287</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 3101 1074	China:	+86 10 5100 3039	Middle East / Africa (Arabic-speaking countries):	+961 3 487 287	US:	+1 703 527 3887
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### 2. HAZARDS IDENTIFICATION

<b>Fire and Explosion Hazards</b>	This product is classified as a non-combustible solid and will not support propagating combustion.
<b>Health</b>	Caution - Pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. Health effects information is based on hazards of components.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### \* 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
CALCIUM MUPIROCIN DIHYDRATE	115074-43-6	3	
Other components below reportable levels		97	

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## 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>	Physical form suggests that risk of inhalation exposure is negligible.
<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>	None.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Antidotes</b>	No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<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.

## 6. ACCIDENTAL RELEASE MEASURES

<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>	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

<b>HANDLING</b>	
<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>STORAGE</b>	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## OCCUPATIONAL EXPOSURE LIMITS

<b>INGREDIENT</b>	CALCIUM MUPIROCIN DIHYDRATE
<b>GSK Occupational Hazard Category</b>	1
<b>GSK Occupational Exposure Limit</b>	5000 mcg/m <sup>3</sup> (8 HR TWA)

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**ENGINEERING CONTROLS**

<b>Exposure Controls</b>	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.
<b>Other Equipment or Procedures</b>	Wash hands and arms thoroughly after handling. None required for normal handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

<b>Physical Form</b>	Cream.
<b>Flash Point</b>	120 °C (Closed Cup).

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

<b>Pharmacological Effects</b>	This preparation contains ingredient(s) with the following activity: an antibiotic.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Minor irritation might occur following direct contact with eyes.
<b>Sensitisation</b>	Sensitisation (allergic skin reaction) is not expected.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	No adverse effects have been reported following extensive use or exposure in humans.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	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.
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**ECOTOXICITY****Aquatic**

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

**MOBILITY**

<b>Solubility</b>	This material contains an active ingredient that for environmental fate predictions has solubility in water.
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## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	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.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this product.

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## \* 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** Not regulated in transport.

## \* 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.

**Other US Regulations**

**TSCA Status** Exempt

## 16. OTHER INFORMATION

**References** GSK Hazard Determination

**SDS Version Number** 9

**SDS Sections Updated****Sections**

COMPOSITION / INFORMATION ON INGREDIENTS  
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY  
REGULATORY INFORMATION  
TRANSPORT INFORMATION

**Subsections**

US OSHA Standard (29 CFR Part 1910.1200) - Classification

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.