SAFETY DATA SHEET

1. Identification

Product identifier **BACTROBAN CREAM**

Other means of identification Not available.

Synonym(s) BACTROBAN CREAM (MUPIROCIN CALCIUM CREAM) 2% * BACTROBAN CREAM 2% * MUPIROCIN CALCIUM * MUPIROCIN CALCIUM, FORMULATED PRODUCT

Recommended use Medicinal Product

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.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
CETOMACROGOL 1000 BP	ETHOXY (20-24) CETOSTEARYL ALCOHOL ETHOXYLATED CETOSTEARYL ALCOHOL ALCOHOLS, C16-C18), ETHOXYLATED CETOSTEARYL ALCOHOL ETHOXYLATED LUTENSOL AT 50 TALLOW ALCOHOL D1000246	68439-49-6	6

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
CETYL ALCOHOL	1-HEXADECANOL HEXADECYL ALCOHOL 1-CETANOL CETAL CETANOL CETYLIC ALCOHOL CETYLOL HEXADECANOL N-1-HEXADECANOL N-CETYL ALCOHOL N-HEXADECANOL 1-HEXADECYL ALCOHOL 1-NAXADECANOL CETEARYL ALCOHOL CETO-STEARYL ALCOHOL ALCOHOLS, C16-C19 HEXADECAN-1-OL PALMITYL ALCOHOL PALMITIC ALCOHOL C16H34O OHS04525 RTECS MM0225000	36653-82-4	3.5
CALCIUM MUPIROCIN DIHYDRATE	MUPIROCIN CALCIUM HYDRATE CALCIUM MUPIROCIN DIHYDRATE CALCIUM PSEUDOMONATE A DIHYDRATE CALCIUM MUPIROCIN (STERILE) [2S-[2ALPHA(E),3BETA,4BETA,5ALPHA[2R, HYDROXY-1-METHYLPROPYL) OXIRANYL]METHYL]-2H-PYRAN-2-YL]-2-BU ACID, CALCIUM SALT(2:1), DIHYDRATE NONANOIC ACID, 9-((3-METHYL-1-OXO-4-(TETRAHYDRO-3,4 OXIRANYL)METHYL)-2H-PYRAN-2-YL)-2-BI CALCIUM SALT (2:1) DIHYDRATE (2S-(2ALPHA(E),3BETA,4BETA,5ALPHA(2R BRL-4910-F BRL-4910PS-F	115074-43-6	2.0 - 3.0
BENZYL ALCOHOL	BENZENEMETHANOL BENZENECARBINOL (HYDROXYMETHYL)BENZENE ALPHA-HYDROXYTOLUENE PHENYLCARBINOL PHENYLMETHANOL PHENYLMETHYL ALCOHOL ALPHA-TOLUENOL C7H8O OHS02800 RTECS DN3150000	100-51-6	1
PHENOXYETHANOL	2-Phenoxyethanol ethylene glycol phenyl ether ethylene glycol monophenyl ether phenoxyethyl alcohol phenyl cellosolve	122-99-6	0.5
Other components below reportable levels			86.444

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); irritation.

Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from the fire area if possible without increased personal risk. Cool containers exposed to heat with water spray and remove container, if no risk is involved.
Specific methods	Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear protective clothing and equipment consistent with the degree of hazard. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Collect and place it in a suitable, properly labelled container for recovery or disposal. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS. Detergent solutions can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.
Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and storage

Precautions for safe handling	Avoid prolonged or repeated contact with skin. Use only in well-ventilated areas. No special control measures required for the normal handling of this product.
Conditions for safe storage, including any incompatibilities	Keep away from heat and sources of ignition. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS). No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
MUPIROCIN CALCIUM (CAS 115074-43-6)	8 HR TWA	5000 mcg/m3
	OHC	1

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
BENZYL ALCOHOL (CAS 100-51-6)	TWA	44.2 mg/m3
		10 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Occupational Exposure Limits are not relevant to the current physical form of the product.
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection	Chemical goggles are recommended.

Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Cream.
Color	Off-white.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	248 °F (120 °C) estimated
Flash point	> 248 °F (> 120 °C) Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	Strong oxidizing agents.
Chemical stability	Not available.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Not expected to occur during normal handling of this product.

Skin contact No adverse effects due to skin contact are expected.

Eye contact Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); Irritation.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
Acute		
Inhalation		
LC50	Rat	1000 ppm
Oral		
LD50	Rat	1230 mg/kg
CALCIUM MUPIROCIN DIHYDRATE (CAS 115074-43-6)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
CETOMACROGOL 1000 BP (CAS 68439-49-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
CETYL ALCOHOL (CAS 36653-82-4)		
Acute		
Oral		
LD50	Rat	5 g/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Irritation Corrosion - Skin

CALCIUM MUPIROCIN DIHYDRATE — Acute dermal irritation, Primary dermal irritation index = 0; Mupirocin free acid tested
Result: Negative
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

CALCIUM MUPIROCIN DIHYDRATE — Acute ocular irritation, Kay and Calandra score = 3
Result: Minimal Irritant
Species: Rabbit

Respiratory sensitization Not available.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

CALCIUM MUPIROCIN DIHYDRATE — Maximisation assay (Magnusson and Kligman), Mupirocin free acid tested
Result: Negative
Species: Guinea pig

Germ cell mutagenicity Based on available data, the classification criteria are not met.

CALCIUM MUPIROCIN DIHYDRATE — Ames Assay, GLP assay
Result: Negative
Chromosomal Aberration Assay In Vitro, human lymphocytes
Result: Negative
Micronucleus Assay
Result: Negative
Species: Mouse
Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay
Result: Negative
Sister Chromatid Exchange
Result: Negative
Unscheduled DNA Synthesis, in vivo - in vitro
Result: Negative
Species: Rat

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

CALCIUM MUPIROCIN DIHYDRATE	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

CALCIUM MUPIROCIN DIHYDRATE	Embryo-foetal development - Subcutaneous, Subcutaneous dosing; maximum dose equivalent to 22X maximum human topical daily dose (about 60 mg) on a body surface basis Result: Negative Species: Rat Embryo-foetal development - Subcutaneous, Subcutaneous dosing; maximum dose equivalent to 43X maximum human topical daily dose (about 60 mg) on a body surface basis Result: Negative Species: Rabbit Fertility and general reproductive performance, Subcutaneous dosing; maximum dose equivalent to 14X maximum human topical daily dose (about 60 mg) on a body surface basis Result: Negative Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)			
Acute			
Algae	EC50	Green algae (Scenedesmus quadricauda)	640 mg/l, 96 hours
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Mixed industrial/residential sludge.	2100 mg/l, 49 hours
Crustacea	EC50	Water flea (Daphnia magna)	360 mg/l, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	10 mg/l, 96 hours, Static test
		Fathead minnow (Adult Pimephales promelas)	460 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	63.7 mg/l, 15 minutes
CALCIUM MUPIROCIN DIHYDRATE (CAS 115074-43-6)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Nominal
	NOEC	Daphnia	1000 mg/l
CETYL ALCOHOL (CAS 36653-82-4)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	676 mg/l, 96 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 1000 mg/l, 96 hours
		Fathead minnow (Adult Pimephales promelas)	> 500 mg/l, 5 days

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Photolysis

Half-life (Photolysis-atmospheric)

BENZYL ALCOHOL	2 Days Estimated
CETYL ALCOHOL	16.7 Hours Estimated

Biodegradability

Percent degradation (Anaerobic biodegradation)

BENZYL ALCOHOL	100 %, 14 days Serum Bottle, Anaerobic sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

BENZYL ALCOHOL	1.1
PHENOXYETHANOL	1.16
CALCIUM MUPIROCIN DIHYDRATE	2.45 (Calculated)

Bioconcentration factor (BCF)

BENZYL ALCOHOL	4 Estimated
CETYL ALCOHOL	> 9999 Measured

Mobility in soil Not available.

Adsorption

Soil/sediment sorption - log Koc

BENZYL ALCOHOL	< 0.7 Measured
CETYL ALCOHOL	3.58 - 4.67 Estimated

Mobility in general

Volatility

Henry's law

BENZYL ALCOHOL	0 atm m^3/mol, 25 C Estimated
CETYL ALCOHOL	0.000073 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

CALCIUM MUPIROCIN DIHYDRATE	0.3 (Calculated)

Octanol/water distribution coefficient pH

CALCIUM MUPIROCIN DIHYDRATE	7

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Observe all local and national regulations when disposing of this product. 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

PHENOXYETHANOL (CAS 122-99-6) LISTED

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

PHENOXYETHANOL (CAS 122-99-6)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations 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.

US. Massachusetts RTK - Substance List

BENZYL ALCOHOL (CAS 100-51-6)

US. New Jersey Worker and Community Right-to-Know Act

PHENOXYETHANOL (CAS 122-99-6) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

BENZYL ALCOHOL (CAS 100-51-6)
PHENOXYETHANOL (CAS 122-99-6)

US. Rhode Island RTK

PHENOXYETHANOL (CAS 122-99-6)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	09-24-2013
Revision date	09-24-2013
Version #	12
Further information	This material has not been assessed for HMIS or NFPA ratings.
References	GSK Hazard Determination
Disclaimer	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.
Revision Information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Reports Toxicological Information: Transport Information: GHS: Classification