SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	BACTROBAN CREAM
Registration number	-
Synonyms	BACTROBAN CREAM (MUPIROCIN CALCIUM CREAM) 2% * BACTROBAN CREAM 2% * MUPIROCIN CALCIUM * MUPIROCIN CALCIUM, FORMULATED PRODUCT
Issue date	24-September-2013
Version number	12
Revision date	24-September-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards This product will support combustion at elevated temperatures.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.
No information is available about the potential of this product to produce adverse environmental effects.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
CETOMACROGOL 1000 BP	5 - < 10	68439-49-6 500-212-8	-	-	
Classification: **DSD:** Xi;R36-38					
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319					
CETYL ALCOHOL	3 - < 5	36653-82-4 253-149-0	-	-	
Classification: **DSD:** Xi;R38					
CLP: Skin Irrit. 2;H315					
CALCIUM MUPIROCIN DIHYDRATE	2.0 - 3.0	115074-43-6 -	-	-	
Classification: **DSD:** -					
CLP: -					
Benzyl alcohol	1 - < 3	100-51-6 202-859-9	-	603-057-00-5	
Classification: **DSD:** Xn;R20/22					
CLP: Acute Tox. 4;H302, Acute Tox. 4;H332					
PHENOXYETHANOL	< 1	122-99-6 204-589-7	-	603-098-00-9	
Classification: **DSD:** Xn;R22, Xi;R36					
CLP: Acute Tox. 4;H302, Eye Irrit. 2;H319					
Other components below reportable levels	80 - < 90				

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of 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 medical advice. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

4.2. Most important symptoms and effects, both 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.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards This product will support combustion at elevated temperatures.

5.1. Extinguishing media

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Wear protective clothing and equipment consistent with the degree of hazard. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

6.2. Environmental precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

6.3. Methods and material 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. Detergent solutions can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. 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.

7.2. 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.

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

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

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Chemical goggles are recommended. (eg. EN 166)

Skin protection	
- 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Environmental exposure controls	
Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Cream.
Colour	Off-white.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	120 °C (248 °F) estimated
Flash point	> 120 °C (> 248 °F) 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Strong oxidising agents.
10.2. Chemical stability	Not available.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.

10.6. Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

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 The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); Irritation.

11.1. Information on toxicological effects

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 sensitisation Not available.

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

Sensitisation

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.

Germ cell mutagenicity

Mutagenicity

CALCIUM MUPIROCIN DIHYDRATE — Ames Assay, GLP assay
Result: negative

Mutagenicity

CALCIUM MUPIROCIN DIHYDRATE

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

CALCIUM MUPIROCIN DIHYDRATE

SAR / QSAR, DEREK, Lhasa, UK
Result: negative

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

Reproductive toxicity

Reproductivity

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.

Mixture versus substance information No information available.

Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity

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

Components		Species	Test results
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.

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

Benzyl alcohol	2 Days Estimated
CETYL ALCOHOL	16.7 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CETYL ALCOHOL	0.4 %, < 1 day Other degradation test system, Activated sludge 30 - 60 %, 5 days BOD5

Percent degradation (Aerobic biodegradation-ready)

Benzyl alcohol	> 90 %, 30 days Closed Bottle test, Activated sludge

Percent degradation (Anaerobic biodegradation)

Benzyl alcohol	100 %, 14 days Serum Bottle, Anaerobic sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

Benzyl alcohol	1.1
CALCIUM MUPIROCIN DIHYDRATE	2.45 (calculated)
PHENOXYETHANOL	1.16

Bioconcentration factor (BCF)

Benzyl alcohol	4 Estimated
CETYL ALCOHOL	> 9999 Measured

12.4. 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

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Benzyl alcohol (CAS 100-51-6)
PHENOXYETHANOL (CAS 122-99-6)

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R20/22 Harmful by inhalation and if swallowed. R22 Harmful if swallowed. R36 Irritating to eyes. R38 Irritating to skin. H302 Harmful if swallowed. H315 Causes skin irritation. H319 Causes serious eye irritation. H332 Harmful if inhaled.
Revision information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Reports TOXICOLOGICAL INFORMATION: Transport Information: Agency Name and Packaging Type/Transport Mode Selection GHS: Classification
Training information	Follow training instructions when handling this material.
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.