

## 1. Identification

### Product identifier

**BACTROBAN OINTMENT**

### Other means of identification

#### Synonyms

BACTROBAN 2% OINTMENT \* MUPIROCIN OINTMENT, 2% \* SPECTRODERM OINTMENT \* EISMYCIN OINTMENT \* 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. Medicinal Product

### 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

Chemical name	Common name and synonyms	CAS number	%
POLYETHYLENE GLYCOLS	GLYCOLS, POLYETHYLENE * ETHYLENE GLYCOL HOMOPOLYMER * ETHYLENE GLYCOL POLYMER * ETHYLENE OXIDE POLYMER * ETHYLENE POLYOXIDE * ALPHA, OMEGA-HYDROXYPOLY(ETHYLENE OXIDE) * POLY(ETHYLENE OXIDES) * POLY(ETHYLENE ETHER) GLYCOL * ALPH-HYDRO-OMEGA-HYDROXY POLY(OXY-1,2-ETHANEDIYL) * POLYETHYLENE GLYCOL * POLY(VINYL OXIDE) * 1,2-ETHANEDIOL, MONOPOLYMER * POLYETHYLENE OXIDE * OXIRANE POLYMER * CARBOWAX * PEG * C6H6O2 * OHS19120 * RTECS TQ3500000	25322-68-3	98

Chemical name	Common name and synonyms	CAS number	%
MUPIROCIN CALCIUM	<p>MUPIROCIN CALCIUM HYDRATE *</p> <p>CALCIUM MUPIROCIN DIHYDRATE *</p> <p>CALCIUM PSEUDOMONATE A</p> <p>DIHYDRATE * CALCIUM MUPIROCIN (STERILE) *</p> <p>[2S-[2ALPHA(E),3BETA,4BETA,5ALPHA[2R [3-METHYL-1-OXO-4-(TETRAHYDRO-3,4-DIHYDROXY-5-[[3-(2-HYDROXY-1-METHYLPROPYL) OXIRANYL]METHYL]-2H-PYRAN-2-YL]-2-B UTENYL]OXY]NONANOIC ACID, CALCIUM SALT(2:1), DIHYDRATE * NONANOIC ACID, 9-((3-METHYL-1-OXO-4-(TETRAHYDRO-3,4-DIHYDROXY-5-((3-(2-HYDROXY-1-METHYLPROPYL) OXIRANYL]METHYL)-2H-PYRAN-2-YL)-2-B UTENYL]OXY)-, CALCIUM SALT (2:1) DIHYDRATE (2S-(2ALPHA(E),3BETA,4BETA,5ALPHA(2R*,3R*(1R*,2R*)))) - * BRL-4910-F * BRL-4910PS-F</p>	115074-43-6	2

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

#### 4. First-aid measures

<b>Inhalation</b>	If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); Irritation.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up** Use water spray to reduce vapors or divert vapor cloud drift. Following product recovery, flush area with water.

**Environmental precautions** Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.  
Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** No special control measures required for the normal handling of this product.

**Conditions for safe storage, including any incompatibilities** Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

##### Components

##### Type

##### Value

MUIPIROCIN CALCIUM  
(CAS 115074-43-6)

8 HR TWA

5000 mcg/m3

OHC

1

#### US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

##### Components

##### Type

##### Value

##### Form

POLYETHYLENE  
GLYCOLS (CAS  
25322-68-3)

TWA

10 mg/m3

Particulate.

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

### Exposure guidelines

#### 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

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

##### Hand protection

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

##### Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

#### Respiratory protection

No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

#### 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

Ointment.

#### 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

Not available.

#### Flash point

> 572 °F (> 300 °C) Closed Cup

#### Evaporation rate

Not available.

<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. Not expected to occur during normal handling of this product.
<b>Skin contact</b>	No adverse effects due to skin contact are expected. Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.

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

<b>Acute toxicity</b>	Expected to be a low ingestion hazard.
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Components	Species	Test Results
MUPIROCIN CALCIUM (CAS 115074-43-6)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg

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

<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
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**Irritation Corrosion - Skin**  
**MUPIROCIN CALCIUM**

Acute dermal irritation, Primary dermal irritation index = 0;  
Mupirocin free acid tested  
Result: Non-irritant  
Species: Rabbit

**Serious eye damage/eye irritation**

Based on available data, the classification criteria are not met. Direct contact with eyes may cause temporary irritation.

**Eye**

**MUPIROCIN CALCIUM**

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

**Respiratory or skin sensitization**

**Respiratory sensitization**

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

**Skin sensitization**

Based on available data, the classification criteria are not met. This product is not expected to cause skin sensitization.

**Sensitization**

**MUPIROCIN CALCIUM**

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.

**Mutagenicity**

**MUPIROCIN CALCIUM**

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**

**MUPIROCIN CALCIUM**

Carcinogenic effects are not expected as a result of occupational exposure.

SAR / QSAR, DEREK, Lhasa, UK  
Result: No structural alerts identified.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity**

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

**Reproductivity**

**MUPIROCIN CALCIUM**

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.

<b>Aspiration hazard</b>	Not available.
<b>Further information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
MUPIROCIN CALCIUM (CAS 115074-43-6)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Nominal
	NOEC	Daphnia	1000 mg/l

\* 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.

**Bioaccumulative potential** Not available.

### Partition coefficient n-octanol / water (log Kow)

MUPIROCIN CALCIUM 2.45 (Calculated)

**Mobility in soil** Not available.

**Mobility in general** Not available.

### Distribution

#### Octanol/water distribution coefficient log DOW

MUPIROCIN CALCIUM 0.3 (Calculated)

#### Octanol/water distribution coefficient pH

MUPIROCIN CALCIUM 7

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**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). Avoid discharge into water courses or onto the ground.

**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 dangerous goods.

### IMDG

Not regulated as dangerous goods.

**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)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<b>Hazard categories</b>	Immediate Hazard - Yes
	Delayed Hazard - No
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

<b>SARA 311/312 Hazardous chemical</b>	No
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**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

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

Not regulated.

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
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**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

Not regulated.

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

Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**

Not listed.

**US. Rhode Island RTK**

Not regulated.

**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**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
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

<b>Issue date</b>	11-10-2014
<b>Revision date</b>	11-10-2014
<b>Version #</b>	16
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	This document has undergone significant changes and should be reviewed in its entirety.