



SAFETY DATA SHEET

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 of the chemical and restrictions on use

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

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
MUPIROCIN CALCIUM MUPIROCIN CALCIUM HYDRATE CALCIUM MUPIROCIN DIHYDRATE CALCIUM PSEUDOMONATE A DIHYDRATE CALCIUM MUPIROCIN (STERILE) [2S-[2ALPHA(E),3BETA,4BETA,5ALPHA[2R,3R(1R,2R)]]]-9-[[3-METHYL-1-OXO-4-[TETRAHYDRO-3,4-DIHYDROXY-5-[[3-(2-HYDROXY-1-METHYLPROPYL)OXIRANYL]METHYL]-2H-PYRAN-2-YL]-2-BUTENYL]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-BUTENYL)OXY)-, CALCIUM SALT (2:1) DIHYDRATE (2S-(2ALPHA(E),3BETA,4BETA,5ALPHA(2R*,3R*(1R*,2R*))))- BRL-4910-F BRL-4910PS-F	115074-43-6	2

Other components below reportable levels

98

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

4. First-aid measures

Description of necessary first aid measures

Inhalation	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.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

Personal protection for first-aid responders In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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

Medical attention and special treatment 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 centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

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

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem Code Not available.

General fire hazards No unusual fire or explosion hazards noted.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. For personal protection, see section 8.

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

Environmental precautions Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Extinguish all flames in the vicinity. Use water spray to reduce vapours or divert vapour cloud drift. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

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. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK

Components

	Type	Value
MUPIROCIN CALCIUM (CAS 115074-43-6)	8 HR TWA	5000 mcg/m ³
	OHC	1

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, for example personal protective equipment (PPE)

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.

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.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Ointment.

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	Not available.
Flash point	> 300 °C (> 572 °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.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	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	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation	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.
Skin contact	No adverse effects due to skin contact are expected. Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to exposure	The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); Irritation.

Acute toxicity Expected to be a low ingestion hazard.

Components	Species	Test results
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MUPIROCIN CALCIUM (CAS 115074-43-6)

Acute

Oral

LD50

Rat

> 5000 mg/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
MUPIROCIN CALCIUM

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

Serious eye damage/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 sensitisation

Respiratory sensitisation

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

Skin sensitisation

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

Sensitisation

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.

Reproductive toxicity

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

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

None known.

Aspiration hazard

Not available.

Other information

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)

Aquatic

Acute

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	
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 methods	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.
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). 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

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 Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

The product does not need to be labelled in accordance with EC directives or respective national laws.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Country(s) or region	Inventory name	On inventory (yes/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

Issue date	10-November-2014
Revision date	10-November-2014
References	ACGIH EPA: AQUIRE database NLM: Hazardous Substances Data Base US. IARC Monographs on Occupational Exposures to Chemical Agents 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: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Proper Shipping Name/Packing Group Regulatory Information: United States GHS: Classification