



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** MUPIROCIN OINTMENT

### Other means of identification

#### Synonyms

MUPIROCIN 2% OINTMENT (ANZ) \* BACTROBAN OINTMENT \* MUPIDAR OINTMENT \* MUIPISKIN OINTMENT \* SPECTRODERM OINTMENT \* T-BACT OINTMENT \* MUPIROCIN CALCIUM, FORMULATED PRODUCT \* 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 Pharmaceuticals and Vaccines  
1061 Mountain Highway  
Melbourne, Victoria 3155  
Australia

General Information Phone Number (Normal Business Hours): (03) 9721 6000

GlaxoSmithKline Australia Consumer Healthcare  
82 Hughes Avenue  
Ermington NSW 2115  
Australia

General Information Phone Number (Normal Business Hours): 1800 028 533 or  
(02) 9684 0888

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#### CHEMTREC TRANSPORTATION EMERGENCY NUMBERS

Customer Number: CCN9484

(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

**Physical hazards** Not classified.

**Health hazards** Not classified.

**Environmental hazards** Not classified.

### Label elements, including precautionary statements

**Hazard symbol(s)** None.

**Signal word** None.

**Hazard Statement(s)** The mixture does not meet the criteria for classification.

#### Precautionary Statement(s)

**Prevention** Not available.

**Response** Not available.

**Storage** Not available.

<b>Disposal</b>	Not available.
<b>Other hazards which do not result in classification</b>	This product will support combustion at elevated temperatures. Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.
<b>Supplemental information</b>	None.

### 3. Composition/information on ingredients

#### Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
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	>95
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-O XO-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-HYDROX Y-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	<5

\*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

<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 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** Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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 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** None.

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

**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** Keep away from heat, sparks and open flame. Avoid release to the environment.

**Conditions for safe storage, including any incompatibilities** Keep away from heat, sparks and open flame. 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 <sup>3</sup>
	OHC	1

#### Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
POLYETHYLENE GLYCOLS (CAS 25322-68-3)	TWA	1000 mg/m <sup>3</sup>	Inhalable fraction.

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

### Exposure guidelines

<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, for example personal protective equipment (PPE)</b>	
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Liquid.
<b>Form</b>	Ointment.
<b>Colour</b>	Off-white.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	> 300 °C (> 572 °F) Closed cup
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<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>Vapour pressure</b>	Not available.
<b>Vapour 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>	Keep away from heat, sparks and open flame. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising 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 possible 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 exposure</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>Acute toxicity</b>	Expected to be a low ingestion hazard.

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

#### Acute

##### Oral

LD50	Rat	> 5000 mg/kg
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\* 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
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**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
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### 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
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**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
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**Mutagenicity**  
MUPIROCIN CALCIUM

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**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**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**

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

MUPIROCIN CALCIUM

2.45 (calculated)

**Mobility in soil**

No data available.

**Mobility in general**

**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 established.

## 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.) Additional information is given in the Material Safety Data Sheet.

All ingredients in this product are listed on the Australian Inventory of Chemical Substances (AICS) or are exempt.

This product is a medicine. (AUST R 11199).

Poison Standard (SUSMP) Schedule: (S4) Prescription Only Medicine.

#### Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

#### High Volume Industrial Chemicals (HVIC)

Not listed.

#### Importation of Ozone Deleting 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.

## 16. Other information

**Issue date** 10-November-2014

**Revision date** 04-November-2016

**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**

This document has undergone significant changes and should be reviewed in its entirety.