SAFETY DATA SHEET

1. Identification

Product identifier **NEOSPORIN OINTMENT**

Other means of identification

Synonyms NEOSPORIN ANTIBIOTIC OINTMENT * NEOSPORIN SKIN OINTMENT * NEOSPORIN TOPICAL OINTMENT * NEOSPORIN UNGUENTO DERMICO * NEOMYCIN AND POLYMIXIN B SULFATES AND BACITRACIN ZINC OINTMENT USP * BACITRACIN ZINC, NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE, 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.

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
PHARMACEUTICAL GRADE PETROLATUM PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP PETROLATO (PETROLIO) Petrolatum PRETOLATO PÉTROLATUM VASELIN	8009-03-8	>97.0

NEOMYCIN SULFATE NEOMYCIN, SULFATE (SALT) NEOMYCIN SULPHATE MYCERIN SULPHATE 242 (GW ACN) MYCIGUENT NEOMIX NEOMYCIN SULFATE USP POWDER 50/50	1405-10-3	<1.0
POLYMYXIN B SULFATE GR214114X 1732 (GW ACN) AEROSPORIN POLYMYXIN B SULPHATE	1405-20-5	<1.0
ZINC BACITRACIN BACITRACIN ZINC BACIFERM ZINC-BACITRACIN BACITRACIN, ZINC SALT 93Z59 GR 31385A	1405-89-6	<1.0

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. 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). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
Symptoms caused by exposure	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching).
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 (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 fire fighters	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	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. Keep upwind. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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	Avoid discharge into drains, water courses or onto the ground.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapours or divert vapour cloud drift. 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. Prevent entry into waterways, sewer, basements or confined areas. 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 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	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a well-ventilated place. 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	Note
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m3	
	OHC	1	Reproductive hazard
		1	SKIN SENSITISER
POLYMYXIN B SULFATE (CAS 1405-20-5)	8 HR TWA	100 mcg/m3	
	OHC	3	
ZINC BACITRACIN (CAS 1405-89-6)	8 HR TWA	1500 mcg/m3	
	OHC	1	

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.

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
ZINC BACITRACIN (CAS 1405-89-6)	TWA	2 mg/m3	Inhalable fraction.
		0.1 mg/m3	Respirable fraction.

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

Exposure guidelines Not available.

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. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves.

Other Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection 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 Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. 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 Not available.

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 182 - 221 °C (359.6 - 429.8 °F) Closed cup (Estimation based on components).

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	Keep away from heat, sparks and open flame. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	None known. 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.
NEOMYCIN SULFATE	Literature search Result: May cause irritation
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use.
Symptoms related to exposure	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching)
Acute toxicity	Health injuries are not known or expected under normal use.

Components	**Species**	**Test results**
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
Oral		
LD50	Mouse	> 8000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000 mg/kg, 2 years
POLYMYXIN B SULFATE (CAS 1405-20-5)		
Acute		
Oral		
LD50	Mouse	790 mg/kg

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. Health injuries are not known or expected under normal use.

Corrosivity

NEOMYCIN SULFATE — Literature search
Result: Irritant

Corrosivity

POLYMYXIN B SULFATE	Literature search Result: May cause irritation
ZINC BACITRACIN	Literature search Result: May cause irritation

Serious eye damage/irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

POLYMYXIN B SULFATE	Acute ocular irritation Result: Non-Irritating Species: Rabbit
NEOMYCIN SULFATE	Literature search Result: Irritant

Respiratory or skin sensitisation

Respiratory sensitisation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

NEOMYCIN SULFATE	Literature search Result: positive

Skin sensitisation Health injuries are not known or expected under normal use.

Sensitisation

POLYMYXIN B SULFATE	Clinical use Result: Hypersensitvity reactions can occur rarely in patients.
ZINC BACITRACIN	Literature search Result: Rare cases of allergic and anaphylactic reactions from clinical use.
NEOMYCIN SULFATE	Literature search Result: positive

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Not expected to be genotoxic under occupational exposure conditions. Health injuries are not known or expected under normal use.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Contains a material (petrolatum) classified as a carcinogen by external agencies. These effects are suspected to be due to impurities that are not expected to be present in purified material used in this product. Health injuries are not known or expected under normal use.

NEOMYCIN SULFATE	25 mg/kg/day, Auditory toxicity, no evidence of carcinogenicity. Species: Rat Observation Period: 104 weeks
PHARMACEUTICAL GRADE PETROLATUM	>= 3000 mg/kg/day 2 year bioassay, oral administration Result: NOAEL Species: Rat Dermal application Result: negative Species: Mouse

ACGIH Carcinogens

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	A2 Suspected human carcinogen.
	A4 Not classifiable as a human carcinogen.

Reproductive toxicity Not expected to produce adverse effects on fertility or development under occupational exposure conditions. Health injuries are not known or expected under normal use.

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.

POLYMYXIN B SULFATE	Clinical use Result: High doses can cause respiratory irritation. Organ: Lungs
NEOMYCIN SULFATE	Organ: Auditory system, kidneys.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

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
ZINC BACITRACIN (CAS 1405-89-6)			
Aquatic			
Acute			
Algae	NOEC	Algae	> 10 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	34 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	74 mg/l, 96 hours

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

Persistence and degradability Not available.

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ZINC BACITRACIN > 50 %, 20 Days

Bioaccumulative potential Not available.

Mobility in soil No data available for this product.

Mobility in general Not available.

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting.

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

ZINC BACITRACIN (CAS 1405-89-6)	for human internal use Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 5

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	Exception may apply, see the regulation for relevance.

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.

Australia National Pollutant Inventory (NPI): Threshold quantity

ZINC BACITRACIN (CAS 1405-89-6)	10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	1000 - 9999 TONNES See the regulation for additional information.

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.

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

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

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)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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 12-December-2014

Revision date 12-December-2014

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: Product and Company Identification
Hazards Identification: EU Hazard Classifications
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: Risk Phrases - Class.