

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

1.1. Product identifier

Trade name or designation of the mixture	NEOSPORIN OINTMENT
Registration number	-
Synonyms	NEOSPORIN ANTIBIOTIC OINTMENT * NEOSPORIN SKIN OINTMENT * NEOSPORIN TOPICAL OINTMENT * NEOSPORIN UNGUENTO DERMICO * NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC OINTMENT USP * BACITRACIN ZINC, NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE, FORMULATED PRODUCT
Issue date	12-December-2014
Version number	04
Revision date	12-December-2014

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.

2.3. Other hazards

This product will support combustion at elevated temperatures.
See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PHARMACEUTICAL GRADE PETROLATUM	>97.0	8009-03-8 232-373-2	-	649-254-00-X	
Classification:	DSD: -				N
	CLP: -				N
NEOMYCIN SULFATE	<1.0	1405-10-3 215-773-1	-	-	
Classification:	DSD: Xi;R36, R43				
	CLP: Skin Sens. 1;H317, Eye Irrit. 2;H319				
POLYMYXIN B SULFATE	<1.0	1405-20-5 2157747	-	-	
Classification:	DSD: Xn;R22				
	CLP: Acute Tox. 4;H302				
ZINC BACITRACIN	<1.0	1405-89-6 215-787-8	-	-	
Classification:	DSD: R52/53				
	CLP: Aquatic Chronic 3;H412				

List of abbreviations and symbols that may be used above

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).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information 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.

4.1. Description of 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.

4.2. Most important symptoms and effects, both acute and delayed Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching).

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

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	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. 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.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material 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.

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling	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, 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).
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	Note
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m ³	
	OHC	1	Reproductive hazard SKIN SENSITISER
POLYMYXIN B SULFATE (CAS 1405-20-5)	8 HR TWA	100 mcg/m ³	
	OHC	3	
ZINC BACITRACIN (CAS 1405-89-6)	8 HR TWA	1500 mcg/m ³	
	OHC	1	
Ireland. Occupational Exposure Limits Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m ³	Inhalable fraction.

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.
Exposure guidelines	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. 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, 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	If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.
Skin protection	
- Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Not normally needed.
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387). No personal respiratory protective equipment normally required.
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.
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	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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.

Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	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	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Inhalation
NEOMYCIN SULFATE Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
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 Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching)

11.1. Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test results
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 8000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 15 g/kg
Chronic		
<i>Oral</i>		
NOAEL	Rat	>= 3000 mg/kg, 2 years
POLYMYXIN B SULFATE (CAS 1405-20-5)		
Acute		
<i>Oral</i>		
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
POLYMYXIN B SULFATE	Literature search Result: May cause irritation
ZINC BACITRACIN	Literature search Result: May cause irritation
Serious eye damage/eye 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 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: Hypersensitivity 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
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.
Reproductivity	
NEOMYCIN SULFATE	100 mg/kg/day Embryo-foetal development, Intra-muscular administration. Result: Auditory toxicity in offspring. Species: Rat Notes: Shepherd's Catalogue of Teratogenic Agents. 25 mg/kg/day 3-generation study, Dietary study. Result: NOAEL (maximum dose) Species: Rat Notes: WHO Food Additive Series 25 mg/kg/day, Dietary study. Result: No adverse foetal effects observed. Species: Rat Notes: WHO Food Additive Series 4 g/l Embryo-foetal development, Administered in drinking water. Result: No malformations. Species: Mouse Notes: Shepherd's Catalogue of Teratogenic Agents. Embryo-foetal development Result: No malformations. Species: Rabbit Notes: Reprotox

Reproductivity
ZINC BACITRACIN

Literature search
Result: No adverse reproductive effects.
Species: Rabbit

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
Organ: Auditory system, kidneys.

NEOMYCIN SULFATE

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

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

SECTION 12: Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms.

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

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

12.2. Persistence and degradability Not available.

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ZINC BACITRACIN > 50 %, 20 Days

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow) Not available.

12.4. Mobility in soil Not available.

Mobility in general Not available.

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). 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.

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

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(10) 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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

R22 Harmful if swallowed.
R36 Irritating to eyes.
R43 May cause sensitization by skin contact.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

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 and Packaging Type/Transport Mode Selection
Regulatory Information: Risk Phrases - Class.

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.