

## 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 POLYMYXIN B SULFATES AND BACITRACIN ZINC OINTMENT USP \* BACITRACIN ZINC, NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE, 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.

**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	%
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

Chemical name	Common name and synonyms	CAS number	%
ZINC BACITRACIN	BACITRACIN ZINC * BACIFERM * ZINC-BACITRACIN * BACITRACIN, ZINC SALT * 93Z59 * GR 31385A	1405-89-6	<1.0

\*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>	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.
<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>	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching).
<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). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Water.
<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>	This product will support combustion at elevated temperatures.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid breathing mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapors or divert vapor 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.
<b>Environmental precautions</b>	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

<b>Precautions for safe handling</b>	No special control measures required for the normal handling of this product.
<b>Conditions for safe storage, including any incompatibilities</b>	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/personal protection

### Occupational exposure limits

#### GSK

Components	Type	Value	Note
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m3	
	OHC	1	REPRODUCTIVE HAZARD 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	

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	PEL	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.

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

#### 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, such as personal protective equipment

##### 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

Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

##### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

#### General hygiene considerations

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.

<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor 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>	359.6 - 429.8 °F (182 - 221 °C) Closed Cup (Estimation based on components).
<b>Evaporation rate</b>	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>	Keep away from heat, sparks and open flame. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known. 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.
NEOMYCIN SULFATE	Literature search Result: May cause irritation
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching)
<b>Information on toxicological effects</b>	
<b>Acute toxicity</b>	Health injuries are not known or expected under normal use.

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

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

<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation. Health injuries are not known or expected under normal use.	
<b>Corrosivity</b>		
NEOMYCIN SULFATE		Literature search Result: Irritant
POLYMYXIN B SULFATE		Literature search Result: May cause irritation
ZINC BACITRACIN		Literature search Result: May cause irritation
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.	
<b>Eye</b>		
POLYMYXIN B SULFATE		Acute ocular irritation Result: Non-Irritating Species: Rabbit
NEOMYCIN SULFATE		Literature search Result: Irritant
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
NEOMYCIN SULFATE		Literature search Result: Positive
<b>Skin sensitization</b>	Health injuries are not known or expected under normal use.	
<b>Sensitization</b>		
POLYMYXIN B SULFATE		Clinical use Result: Hypersensitivity reactions can occur rarely in patients.
NEOMYCIN SULFATE		Literature search Result: Positive
ZINC BACITRACIN		Literature search Result: Rare cases of allergic and anaphylactic reactions from clinical use.
<b>Germ cell mutagenicity</b>	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.	
<b>Carcinogenicity</b>	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

**Carcinogenicity**

PHARMACEUTICAL GRADE PETROLATUM

&gt;= 3000 mg/kg/day 2 year bioassay, oral administration

Result: NOAEL

Species: Rat

Dermal application

Result: Negative

Species: Mouse

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

Not listed.

**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

Literature search

Result: No adverse reproductive effects.

Species: Rabbit

ZINC BACITRACIN

**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.

**Chronic effects**

Prolonged inhalation may be harmful.

**Further 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)			
<b>Aquatic</b>			
<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.

**Persistence and degradability** Not available.

**Biodegradability**

**Percent degradation (Aerobic biodegradation-soil)**

ZINC BACITRACIN > 50 %, 20 Days

**Bioaccumulative potential** Not available.

**Mobility in soil** Not available.

**Mobility in general** Not available.

**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)**

ZINC BACITRACIN (CAS 1405-89-6) 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)**

**Hazard categories**

Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Chemical name	CAS number	% by wt.
ZINC BACITRACIN	1405-89-6	<1.0

## 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.

### Safe Drinking Water Act (SDWA)

Not regulated.

## 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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

ZINC BACITRACIN (CAS 1405-89-6)

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

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

### US. Rhode Island RTK

ZINC BACITRACIN (CAS 1405-89-6)

### US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

### US - California Proposition 65 - CRT: Listed date/Developmental toxin

NEOMYCIN SULFATE (CAS 1405-10-3)

Listed: October 1, 1992

## 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, including date of preparation or last revision

Issue date	12-12-2014
Revision date	12-12-2014
Version #	04
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
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.