

1. Identification

Product identifier	BACTROBAN NASAL
Other means of identification	Not available.
Synonym(s)	BACTROBAN NASAL (MUIPIROCIN CALCIUM OINTMENT, 2%) * BACTROBAN NASAL OINTMENT 2% * TURIXIN NASAL OINTMENT * TURIXIN NASENSALBE * MUIPIROCIN CALCIUM * MUIPIROCIN CALCIUM, 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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
CALCIUM MUIPIROCIN DIHYDRATE	MUIPIROCIN CALCIUM HYDRATE CALCIUM MUIPIROCIN DIHYDRATE CALCIUM PSEUDOMONATE A DIHYDRATE CALCIUM MUIPIROCIN (STERILE) [2S-[2ALPHA(E),3BETA,4BETA,5ALPHA[2R, HYDROXY-1-METHYLPROPYL) OXIRANYL]METHYL]-2H-PYRAN-2-YL]-2-BL ACID, CALCIUM SALT(2:1), DIHYDRATE NONANOIC ACID, 9-((3-METHYL-1-OXO-4-(TETRAHYDRO-3,4 OXIRANYL)METHYL)-2H-PYRAN-2-YL)-2-BL CALCIUM SALT (2:1) DIHYDRATE (2S-(2ALPHA(E),3BETA,4BETA,5ALPHA(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

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); irritation.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

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 firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.
Specific methods	Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. 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. 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 in original containers for re-use. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	No special control measures required for the normal handling of this product. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Keep away from heat and sources of ignition. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

	Type	Value
MUPIROCIN CALCIUM (CAS 115074-43-6)	8 HR TWA	5000 mcg/m3
	OHC	1

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Occupational Exposure Limits are not relevant to the current physical form of the product.
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, such as personal protective equipment	
Eye/face protection	Not normally needed.

Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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.
Color	Off-white.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	453.2 - 455 °F (234 - 235 °C) 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.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	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	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Not expected to occur during normal handling of this product.

Skin contact	No adverse effects due to skin contact are expected.	
Eye contact	Direct contact with eyes may cause temporary irritation.	
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); Irritation.	
Information on toxicological effects		
Acute toxicity		
Components	Species	Test Results
CALCIUM MUPIROCIN DIHYDRATE (CAS 115074-43-6)		
Acute		
<i>Oral</i>		
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		
CALCIUM MUPIROCIN DIHYDRATE		Acute dermal irritation, Primary dermal irritation index = 0; Mupirocin free acid tested Result: Negative Species: Rabbit
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye		
CALCIUM MUPIROCIN DIHYDRATE		Acute ocular irritation, Kay and Calandra score = 3 Result: Minimal Irritant Species: Rabbit
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Sensitization		
CALCIUM MUPIROCIN DIHYDRATE		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.	
CALCIUM MUPIROCIN DIHYDRATE		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	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
CALCIUM MUPIROCIN DIHYDRATE		SAR / QSAR, DEREK, Lhasa, UK Result: Negative
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	
CALCIUM MUPIROCIN DIHYDRATE		Embryo-foetal development - Subcutaneous, Subcutaneous dosing; maximum dose equivalent to 22X maximum human topical daily dose (about 60 mg) on a body surface basis Result: Negative Species: Rat Embryo-foetal development - Subcutaneous, Subcutaneous dosing; maximum dose equivalent to 43X maximum human topical daily dose (about 60 mg) on a body surface basis Result: Negative Species: Rabbit

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
CALCIUM MUPIROCIN DIHYDRATE (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)

CALCIUM MUPIROCIN DIHYDRATE 2.45 (Calculated)

Mobility in soil Not available.

Mobility in general

Distribution

Octanol/water distribution coefficient log DOW

CALCIUM MUPIROCIN DIHYDRATE 0.3 (Calculated)

Octanol/water distribution coefficient pH

CALCIUM MUPIROCIN DIHYDRATE 7

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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).

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 a dangerous good.

IMDG

Not regulated as a dangerous good.

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)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No
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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.
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Food and Drug Administration (FDA)	Not regulated.
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US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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
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, including date of preparation or last revision

Issue date	09-25-2013
Revision date	09-25-2013
Version #	18
Further information	This material has not been assessed for HMIS or NFPA ratings.
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 Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Reports Toxicological Information: Transport Information: Regulatory Information: United States GHS: Classification