

## SAFETY DATA SHEET



GlaxoSmithKline

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

<b>Material</b>	<b>BETNOVATE N OINTMENT</b>	
<b>Synonyms</b>	BETNOVATE N OINTMENT 0.1% * BETNOVATE-N SALBE * BETNOVATE-N UNGUENTO * BETNEVAL NEOMYCINE POMMADA * BETNOVAT MED NEOMYCIN OINTMENT 0.1%/0.5% * BETAMETHASONE VALERATE AND NEOMYCIN SULPHATE, FORMULATED PRODUCT	
<b>Company Name</b>	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response  GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response	

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
BETAMETHASONE VALERATE	2152-44-5	0.12
NEOMYCIN SULFATE	1405-10-3	0.5
NON-HAZARDOUS INGREDIENTS	Unassigned	99.38

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Caution - Potent pharmaceutical agent. Health effects information is based on hazards of components. May cause steroid withdrawal rash.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### 4. FIRST-AID MEASURES

<b>Ingestion</b>	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS**

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
<b>Antidotes</b>	No specific antidotes are recommended.

**5. FIRE-FIGHTING MEASURES**

<b>* Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible. This product is expected to be non-combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<b>Special Firefighting Procedures</b>	No special firefighting requirements. If possible, contain and collect firefighting water for later disposal.
<b>Hazardous Combustion Products</b>	Toxic or corrosive thermal decomposition products are expected when this material is exposed to fire.

**6. ACCIDENTAL RELEASE MEASURES**

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this product.

**7. HANDLING AND STORAGE****HANDLING**

<b>General Requirements</b>	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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**STORAGE**

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**INGREDIENT** BETAMETHASONE VALERATE

**GSK Occupational Hazard Category** 4

**GSK Occupational Exposure Limit** 10 mcg/m<sup>3</sup> (8 HR TWA) SKIN

**INGREDIENT** NEOMYCIN SULFATE

**GSK Occupational Hazard Category** 1

**GSK Occupational Exposure Limit** 2000 mcg/m<sup>3</sup> (8 HR TWA) SKIN SENSITISER, RESPIRATORY SENSITISER

#### ENGINEERING CONTROLS

**Exposure Controls** 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.

**Other Equipment or Procedures** Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Appearance

**Colour** White.

**Physical Form** Ointment.

### 10. STABILITY AND REACTIVITY

**Stability** This product is expected to be stable.

**Conditions to Avoid** None for normal handling of this product.

### 11. TOXICOLOGICAL INFORMATION

**Oral Toxicity** Not expected to be toxic following ingestion.

**Skin Effects** Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.

**Eye Effects** Minor irritation might occur following direct contact with eyes.

**Target Organ Effects** Adverse effects might occur in the following organ(s) following overexposure: adrenal glands; immune system.

**Sensitisation** Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.

**Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions.

**Carcinogenicity** Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

**Reproductive Effects** Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

**Pharmacological Effects** This material is a selective glucocorticoid receptor agonist. Adverse effects of overexposure might include: suppression of adrenal glands; temporary decrease in white blood cell counts; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); increased susceptibility to infection.

**Other Adverse Effects** None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

**Summary** This material contains an active pharmaceutical ingredient that has been tested, and which may be toxic to aquatic organisms if released directly to the environment. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

### ECOTOXICITY

#### Aquatic

\* **Ecotoxicity** This material contains an active pharmaceutical ingredient that may be toxic to aquatic organisms.

**Activated Sludge Respiration** This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1000 mg/l, 3 Hours, Activated sludge

NOEC: 1000 mg/l, 3 Hours, Activated sludge

\* **Daphnid** This material contains an active pharmaceutical ingredient that is toxic to daphnids.

EC50: 1.9 mg/l, 48 Hours, Daphnia magna, Static test

NOEL: 0.5 mg/l, 48 Hours, Daphnia magna, Static test

### MOBILITY

\* **Adsorption** This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass.

**Partitioning** This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

### PERSISTENCE/DEGRADATION

\* **Hydrolysis** This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: 6.5 Days, Measured, pH 7 Buffer Solution

\* **Biodegradation** This material is inherently biodegradable.

Aerobic - Inherent

Percent Degradation: 28 %, 28 days, Modified MITI (II) Test., Activated sludge

## 13. DISPOSAL CONSIDERATIONS

**Disposal Recommendations** Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

\* **Regulatory Requirements** Observe all local and national regulations when disposing of this product.

## 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification and Labelling**

**Transport Information** Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

<b>15. REGULATORY INFORMATION</b>
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The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.  
For waste disposal purpose, this product should be classified in line with the European Waste Catalogue criteria.

**US OSHA Standard (29 CFR Part 1910.1200)**

**Classification** This product is classified as hazardous according to the OSHA Hazard Communication Standard.

**Other US Regulations**

**TSCA Status** Exempt

<b>16. OTHER INFORMATION</b>
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**References** GSK Hazard Determination

**Date Approved/Revised** 20-Apr-2006

**SDS Version Number** 7

**SDS Sections Updated****Sections**

DISPOSAL CONSIDERATIONS  
ECOLOGICAL INFORMATION

**Subsections**

Regulatory Requirements  
Activated Sludge Respiration  
Adsorption  
Algal  
Algal Degradation  
Bioaccumulation  
Biodegradation  
Crustacea  
Daphnid  
Distribution  
Earthworm  
Ecotoxicity  
EHAC Notation  
Fish  
GSK Environmental Hazard Category  
Hydrolysis  
Microbial Growth Inhibition  
Microtox  
Mobility  
Other Adverse Effects  
Other Species - Aquatic  
Other Species - Terrestrial  
Partitioning  
Persistence/Degradation

**SDS Sections Updated****Sections**

ECOLOGICAL INFORMATION

FIRE-FIGHTING MEASURES

IDENTIFICATION OF SUBSTANCE / PREPARATION AND  
OF COMPANY

REGULATORY INFORMATION

**Subsections**

Photolysis

Solubility

Summary

Volatility

Fire and Explosion Hazards

US Environmental (EPA) Requirements

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.