

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	BETNOVATE RD OINTMENT
Synonyms	BETNOVATE RD OINTMENT 0.025% * BETNOVATE R.D. OINTMENT * BETNOVATE R/D OINTMENT * BETAMETHASONE VALERATE, FORMULATED PRODUCT
Company Name	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 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 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	0.03
NON-HAZARDOUS INGREDIENTS	Unassigned	99.97

3. HAZARDS IDENTIFICATION

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

4. FIRST-AID MEASURES

Ingestion	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.
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Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	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.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	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.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water is recommended for fires involving packaging.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

HANDLING

General Requirements	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 ³ (8 HR TWA)	SKIN

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.

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 20-Apr-2006

SDS Version Number 7

SDS Sections Updated**Sections**

ECOLOGICAL INFORMATION

Subsections

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
Photolysis

SDS Sections Updated**Sections**

ECOLOGICAL INFORMATION

REGULATORY INFORMATION

Subsections

Solubility

Summary

Volatility

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.