SAFETY DATA SHEET

1. Identification

Product identifier **BETNOVATE RD CREAM**

Other means of identification Not available.

Synonym(s) BETNOVATE RD CREAM 0.025% * BETNOVATE R.D.CREAM * BETNOVATE R/D CREAM * BETAMETHASONE VALERATE, 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	%
PHARMACEUTICAL GRADE PETROLATUM	PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP OHS18325 RTECS SE6780000 PETROLATO PETROLATO (PETROLIO) PETROLATOS PETROLATUM PRETOLATO PÉTROLATUM VASELIINI VASELIN VASELINA	8009-03-8	15
LIGHT MINERAL OIL	OHS12791 RTECS PY8047000	8042-47-5	6

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID, MONOHYDRATE CITRIC ACID, MONOHYDRATE CITRIC ACID MONOHYDRATE C6H10O8 OHS84211 RTECS GE7810000	5949-29-1	0.25
BETAMETHASONE VALERATE	CCI 1795 PREGNA-1,4-DIENE-3,20-DIONE,9-FLUORO (11BETA,16BETA)-9-FLUORO-11,21-DIHYD PENTANOATE	2152-44-5	0.03
Other components below reportable levels			78.72

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: burning; itching; pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

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 container from fire area if it can be done without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. 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 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. Use water spray to reduce vapors or divert vapor cloud drift. 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 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 Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Keep away from heat and sources of ignition. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
BETAMETHASONE VALERATE (CAS 2152-44-5)	8 HR TWA	10 mcg/m3	
	OHC	4	SKIN
		4	REPRODUCTIVE HAZARD
HYDROUS CITRIC ACID (CAS 5949-29-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	

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

Components	Type	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	PEL	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	REL	5 mg/m3	Mist.
	STEL	10 mg/m3	Mist.

Biological limit values

No biological exposure limits noted for the ingredient(s).

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.

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

Use personal protective equipment as required.

Respiratory protection

Use personal protective equipment as 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. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers are at greater risk if exposed to the active ingredient which is readily absorbed through the skin. They should not handle unpackaged product. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Ointment.
Color	Not available.
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	> 275 °F (> 135 °C) 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.
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.
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	May be harmful if swallowed.
Inhalation	Prolonged inhalation may be harmful.

Skin contact Pharmacological effects might occur following direct contact with skin. Repeated contact may increase sensitivity of skin to bruising.

Eye contact May be irritating to eyes.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: itching; burning; pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

Information on toxicological effects

Acute toxicity May be harmful in contact with skin. May be harmful if swallowed.

Components	Species	Test Results
BETAMETHASONE VALERATE (CAS 2152-44-5)		
Acute		
Oral		
LD50	Mouse	> 3000 mg/kg
Subacute		
Inhalation		
NOAEL	Dog	12 m/s, 4 weeks, 12 mg/dog
Subchronic		
Dermal		
LOEL	Rabbit	>= 0.15 mg/kg/day, 90 Days, Pharmacological effects
NOEL	Rabbit	0.05 mg/kg/day, 90 Days
LIGHT MINERAL OIL (CAS 8042-47-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 15 g/kg

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

Skin corrosion/irritation Repeated contact may increase sensitivity of skin to bruising.

Corrosivity

BETAMETHASONE VALERATE
Repeated exposure, 0.1 % formulation
Result: Non-irritant
Species: Rabbit
Test Duration: 5 Day
Repeated exposure, 0.1 % formulation
Result: mild irritation resulting from formulation
Species: Rabbit
Test Duration: 14 Day

Serious eye damage/eye irritation May be irritating to eyes.

Eye

BETAMETHASONE VALERATE
0.1 % formulation
Result: Non-Irritating
Species: Rabbit

Respiratory sensitization Not available.

Skin sensitization Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.

Sensitization

BETAMETHASONE VALERATE
Clinical use
Result: very rare (<1/10000)
Species: Human

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

BETAMETHASONE VALERATE
SAR / QSAR, Corticosteroids regarded as minimal risk for genotoxicity
Result: Negative

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.

IARC Monographs. Overall Evaluation of Carcinogenicity

LIGHT MINERAL OIL (CAS 8042-47-5)	3 Not classifiable as to carcinogenicity to humans.

US. National Toxicology Program (NTP) Report on Carcinogens

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	Known To Be Human Carcinogen.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

BETAMETHASONE VALERATE	>= 0.1 mg/kg/day, sub-cutaneous administration Result: developmental effects Species: Mouse >= 0.1 mg/kg/day, sub-cutaneous administration Result: developmental effects Species: Rat >= 12 mcg/kg/day, sub-cutaneous administration Result: developmental effects Species: Rabbit

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure Adrenal glands. Immune system. May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard Not available.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity

Components		Species	Test Results
BETAMETHASONE VALERATE (CAS 2152-44-5)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
	NOEC	Activated sludge	1000 mg/l, 3 hours
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	1.9 mg/l, 48 hours, Static test
	NOEC	Water flea (Daphnia magna)	0.5 mg/l, 48 hours, Static test

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

LIGHT MINERAL OIL	< 1 Days Estimated

Hydrolysis

Half-life (Hydrolysis-neutral)

BETAMETHASONE VALERATE	6.5 Days Measured, pH 7 Buffer Solution

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

BETAMETHASONE VALERATE	3.6 (Measured).

Mobility in soil 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. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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).
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

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

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
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

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.
Food and Drug Administration (FDA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

LIGHT MINERAL OIL (CAS 8042-47-5)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

LIGHT MINERAL OIL (CAS 8042-47-5)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

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)	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)	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	08-27-2013
Revision date	08-27-2013
Version #	09
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: Business Units Composition / Information on Ingredients: Disclosure Overrides Exposure Controls / Personal Protection: Physical & Chemical Properties: Regulatory Information: United States