

1. Identification

Product identifier	BETNOVATE N CREAM
Other means of identification	Not available.
Synonym(s)	BETNOVATE N CREAM 0.1% * BETNOVATE N CREMA * BETNOVATE N CREME * BETNOVATE-N CREAM * BETNOVATE-N CREMA * BETNOVATE-N CREME * BETNOVATE-N SKIN CREAM * BETNEVAL NEOMYCINE CREME * BETNOVAT MED NEOMYCIN CREAM 0.1%/0.5% * ECOVAL N POMATA * BETAMETHASONE VALERATE AND NEOMYCIN SULFATE, 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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
LIGHT MINERAL OIL	OHS12791 RTECS PY8047000	8042-47-5	6
CETAMACROGOL 1000 BP	ETHOXY (20-24) CETOSTEARYL ALCOHOL ETHOXYLATED CETOSTEARYL ALCOHOL ALCOHOLS, C16-C18), ETHOXYLATED CETOSTEARYL ALCOHOL ETHOXYLATED LUTENSOL AT 50 TALLOW ALCOHOL D1000246	68439-49-6	1.8
NEOMYCIN SULFATE	NEOMYCIN, SULFATE (SALT) NEOMYCIN SULPHATE MYCIFRADIN SULFATE MYCERIN SULPHATE 242 (GW ACN) MYCIGUENT NEOMIX OTOBOTIC OHS84263 RTECS QP4375000 NEOMYCIN SULFATE USP POWDER 50/50	1405-10-3	0.5
BETAMETHASONE VALERATE	CCI 1795 PREGNA-1,4-DIENE-3,20-DIONE,9-FLUORC (11BETA,16BETA)-9-FLUORO-11,21-DIHYD PENTANOATE	2152-44-5	0.12
Other components below reportable levels			>97.0

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.
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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
4

SKIN
REPRODUCTIVE
HAZARD

NEOMYCIN SULFATE
(CAS 1405-10-3)

8 HR TWA

2000 mcg/m3

OHC

1
1

SKIN SENSITISER
REPRODUCTIVE
HAZARD

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.

PHARMACEUTICAL
GRADE PETROLATUM
(CAS 8009-03-8)

TWA
REL

5 mg/m3
5 mg/m3

Mist.
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	Use personal protective equipment as required. 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	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.
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Components	Species	Test Results
BETAMETHASONE VALERATE (CAS 2152-44-5)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 3000 mg/kg
Subacute		
<i>Inhalation</i>		
NOAEL	Dog	12 m/s, 4 weeks, 12 mg/dog
Subchronic		
<i>Dermal</i>		
LOEL	Rabbit	>= 0.15 mg/kg/day, 90 Days, Pharmacological effects
NOEL	Rabbit	0.05 mg/kg/day, 90 Days
CETAMACROGOL 1000 BP (CAS 68439-49-6)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
LIGHT MINERAL OIL (CAS 8042-47-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 8000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
<i>Oral</i>		
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.
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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

Components		Species	Test Results
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.

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)	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: Ingredients
Exposure Controls / Personal Protection:
Physical & Chemical Properties:
Transport Information:
Regulatory Information: United States