SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	BETNOVATE N CREAM
Registration number	-
Synonyms	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
Issue date	27-August-2013
Version number	09
Revision date	27-August-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information Not applicable.

2.3. Other hazards This product will support combustion at elevated temperatures.

Caution - Pharmaceutical agent.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PHARMACEUTICAL GRADE PETROLATUM	10 - < 20	8009-03-8 232-373-2	-	649-254-00-X	
Classification: **DSD:** -					
CLP: Carc. 1B;H350					
CETAMACROGOL 1000 BP	1.8	68439-49-6 500-212-8	-	-	
Classification: **DSD:** Xi;R36-38					
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319					
NEOMYCIN SULFATE	0.5	1405-10-3 215-773-1	-	-	
Classification: **DSD:** Xi;R36, R43					
CLP: Skin Sens. 1;H317, Eye Irrit. 2;H319					
BETAMETHASONE VALERATE	0.12	2152-44-5 218-439-3	-	-	
Classification: **DSD:** Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21, N;R51-53					
CLP: Repr. 1B;H360, Repr. 1B;H360D, Repr. 2;H361, Repr. 2;H361f, STOT RE 2;H373, Aquatic Chronic 2;H411					

Other components below reportable levels >97.0

SECTION 4: First aid measures

General information 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.

4.1. Description of 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 centre immediately.

4.2. Most important symptoms and effects, both 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).

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards This product will support combustion at elevated temperatures.

5.1. Extinguishing media

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.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material 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 vapours or divert vapour cloud drift. 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.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. 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).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m3	
	OHC	1	SKIN SENSITISER
		1	Reproductive hazard

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed.

Skin protection

- 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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.

Environmental exposure controls

Hazard guidance and control recommendations	Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Ointment.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	> 135 °C (> 275 °F) 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

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 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).

11.1. 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
CETAMACROGOL 1000 BP (CAS 68439-49-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
Oral		
LD50	Mouse	> 8000 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. Due to partial or complete lack of data the classification is not possible.

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. Due to partial or complete lack of data the classification is not possible.

Eye

BETAMETHASONE VALERATE

0.1 % formulation
Result: Non-Irritating
Species: Rabbit

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Due to partial or complete lack of data the classification is not possible.

Sensitisation

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

Germ cell mutagenicity Due to partial or complete lack of data the classification is not possible.

Germ cell mutagenicity

Mutagenicity

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.

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

Reproductive toxicity

Reproductivity

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. Due to partial or complete lack of data the classification is not possible.

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

Aspiration hazard Not available.

Mixture versus substance information Not available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity

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.

12.2. Persistence and degradability

Persistence and degradability

Hydrolysis

Half-life (Hydrolysis-neutral)

BETAMETHASONE VALERATE — 6.5 Days Measured, pH 7 Buffer Solution

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

BETAMETHASONE VALERATE — 28 %, 28 days Modified MITI (II) Test., Activated sludge

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow)

BETAMETHASONE VALERATE	3.6 (Measured).

12.4. Mobility in soil

Mobility in general

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Directive 94/33/EC on the protection of young people at work

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R36 Irritating to eyes. R38 Irritating to skin. R43 May cause sensitization by skin contact. R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin. R51 Toxic to aquatic organisms. R53 May cause long term adverse effects in the aquatic environment. R61 May cause harm to the unborn child. R62 Possible risk of impaired fertility. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H350 May cause cancer. H360 May damage the unborn child. H360D May damage the unborn child. H361 Suspected of damaging fertility. H361f Suspected of damaging fertility. H373 May cause damage to organs through prolonged or repeated exposure. H411 Toxic to aquatic life with long lasting effects.
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
Training information	Follow training instructions when handling this material.
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.