

1. Identification

Product identifier	BETNOVATE OINTMENT
Other means of identification	Not available.
Synonym(s)	BETNELAN HYDROFOBE OINTMENT 1 MG/G * BETNELAN V OINTMENT * BETNESOL V OINTMENT 0.1% * BETNESOL-V SALBE * BETNEVAL OINTMENT 0.1% * BETNOVAT OINTMENT 0.1% * BETNOVATE Q OINTMENT * ECOVAL UNGUENTO 0.1% * 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	

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 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	98.88

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
LIQUID PARAFFIN	HEAVY LIQUID PARAFFIN PARAFFIN LIQUID, LIGHT LIGHT LIQUID PETROLATUM LIGHT MINERAL OIL LIGHT WHITE MINERAL OIL WHITE MINERAL OIL, (PETROLEUM), LIGHT	92062-35-6	1
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

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.
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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

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value****Form**

LIQUID PARAFFIN (CAS
92062-35-6)

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**

LIQUID PARAFFIN (CAS
92062-35-6)

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**

LIQUID PARAFFIN (CAS
92062-35-6)

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**

Use personal protective equipment as required.

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
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.	
US. National Toxicology Program (NTP) Report on Carcinogens		
LIQUID PARAFFIN (CAS 92062-35-6)	Known To Be Human Carcinogen.	
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	

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
LIQUID PARAFFIN (CAS 92062-35-6)			
Aquatic			
Acute			
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	> 10000 mg/l, 96 hours

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

LIQUID PARAFFIN < 1 Days

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).
 LIQUID PARAFFIN > 6 (Calculated).

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

LIQUID PARAFFIN (CAS 92062-35-6)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

LIQUID PARAFFIN (CAS 92062-35-6)
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

Country(s) or region	Inventory name	On inventory (yes/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)	No
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 #	12
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