SAFETY DATA SHEET

1. Identification

Product identifier **BETNOVATE LOTION**

Other means of identification Not available.

Synonym(s) BETNOVATE 0.1% LOTION * BETNELAN LOTION 1 MG/ML * BETNEVAL LOTION 0.1% * BETNESOL-V LOTION * BETNOVAT KUTAN SOLUTION 1 MG/ML * BETNOVAT SOLUTION * BETNOVAT LOTION * ECOVAL LOZIONE 0.1% * BETAMETHASONE VALERATE, FORMULATED PRODUCT * BETNOVATE LOTION (CONTAINING ISOPROPYL ALCOHOL)

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	%
ISOPROPYL ALCOHOL	ISOPROPANOL ETHYL CARBINOL DIMETHYLCARBINOL 2-PROPANOL ISOHOL SEC-PROPYL ALCOHOL PROPYL ALCOHOL UN 1219 DIMETHYL CARBINOL PROPANOL ISOPROPYL ALCOHOL A.R. 1-METHYLETHANOL 1-METHYLETHYL ALCOHOL 2-HYDROXYPROPANE 2-PROPYL ALCOHOL ISO-PROPANOL ISO-PROPYL ALCOHOL ISOPRANOL LUTOSOL N-PROPAN-2-OL SEC-PROPANOL PROPOL C3H8O OHS12090 RTECS NT8050000 IPA GR 95896X 206W94 85 (GW ACN)	67-63-0	10.2
PARAFFIN OIL	LIQUID PARAFFIN MINERAL OIL WHITE LIQUID PARAFFIN LIQUID PETROLATUM HEAVY MINERAL OIL WHITE MINERAL OIL PARAFFIN OILS OHS17993 RTECS PY8030000 AGUARRÁS MINERAL (VARSOL) MINERAL SOLVENT (VARSOL) NIEBLAS DE ACEITES MINERALES OIL MIST (MINERAL OIL) OIL MIST (MINERAL) OIL, MIST ÖLJYSUMU	8012-95-1	10
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE OSMOGLYN	56-81-5	5

Hazardous components Chemical name	Common name and synonyms	CAS number	%
XANTHAN GUM	1266 (GW ACN) ACTIGUM CX 9 B 1459 BIOPOLYMER 9702 BIOPOLYMER XB 23 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 FLOCON 4800 GALAXY XB KELFLO KELTROL KELTROL (GUM) KELTROL BT KELTROL F KELTROL T KELTROL TF KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 RM 416 RM 578 U 1573 U 2248 XANFLOOD XANTHOMONAS GUM	11138-66-2	0.5
BETAMETHASONE VALERATE	CCI 1795 PREGNA-1,4-DIENE-3,20-DIONE,9-FLUOR((11BETA,16BETA)-9-FLUORO-11,21-DIHYD PENTANOATE	2152-44-5	0.12
SODIUM CITRATE, ANHYDROUS	1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRISODIUM SALT 2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID TRISODIUM SALT 373 (GW ACN) CITNATIN CITREME CITRIC ACID, TRISODIUM SALT CITROSODINA CITROSODINE CITROSODNA E331 NATROCITRAL RM 466 RTECS GE8300000 SODIUM CITRATE SODIUM CITRATE 60/90 TRISODIUM CITRATE URISAL	68-04-2	0.06
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID, MONOHYDRATE CITRIC ACID, MONOHYDRATE CITRIC ACID MONOHYDRATE C6H10O8 OHS84211 RTECS GE7810000	5949-29-1	0.04
Other components below reportable levels			74.08

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Get medical attention immediately.

Skin contact Remove and isolate contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash clothing separately before reuse.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Prolonged exposure may cause chronic effects. 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.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. If you feel unwell, seek medical advice (show the label where possible). Keep victim under observation.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water.
Specific hazards arising from the chemical	Vapors may form explosive mixtures with air. By heating and fire, harmful vapors/gases may be formed. Vapors may travel considerable distance to a source of ignition and flash back. 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. In case of fire and/or explosion do not breathe fumes. Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

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. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. 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	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Keep combustibles (wood, paper, oil, etc.) away from spilled material. 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. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. 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 release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. 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. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. All equipment used when handling the product must be grounded. Static electricity and formation of sparks must be prevented. Use non-sparking tools and explosion-proof equipment. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Avoid prolonged exposure. Avoid contact during pregnancy/while nursing. Use only in well-ventilated areas. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store locked up. Keep away from heat and sources of ignition. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Refrigeration recommended. Keep in an area equipped with sprinklers. 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	
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)	8 HR TWA	5000 mcg/m3	
	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

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

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
ISOPROPYL ALCOHOL (CAS 67-63-0)	PEL	980 mg/m3	
		400 ppm	
PARAFFIN OIL (CAS 8012-95-1)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
ISOPROPYL ALCOHOL (CAS 67-63-0)	STEL	400 ppm	
	TWA	200 ppm	
PARAFFIN OIL (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
ISOPROPYL ALCOHOL (CAS 67-63-0)	STEL	1225 mg/m3	
		500 ppm	
	TWA	980 mg/m3	
		400 ppm	
PARAFFIN OIL (CAS 8012-95-1)	REL	5 mg/m3	Mist.
	STEL	10 mg/m3	Mist.

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
ISOPROPYL ALCOHOL (CAS 67-63-0)	40 mg/l	Acetone	Urine	*

* - For sampling details, please see the source document.

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.

Individual protection measures, such as personal protective equipment

Eye/face protection Eye wash fountain is recommended. Wear approved safety glasses with side shields if eye contact is possible.

Hand protection Wear protective gloves. 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 Normal work clothing (long sleeved shirts and long pants) is recommended.

Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. 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	Not available.
Physical state	Liquid.
Form	Lotion.
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	102.2 - 104 °F (39 - 40 °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	Strong oxidizing agents.
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. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Isocyanates. Acids. Chlorine.
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	Health injuries are not known or expected under normal use.

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; pain; burning; 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
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
ISOPROPYL ALCOHOL (CAS 67-63-0)		
Acute		
Dermal		
LD50	Rabbit	12.8 g/kg
Inhalation		
LC50	Rat	39 mg/l, 8-hr
Oral		
LD50	Rat	5045 mg/kg
Subchronic		
Inhalation		
LOEL	Mouse	1500 ppm
	Rat	1500 ppm
NOEL	Mouse	500 ppm, 13 weeks
	Rat	500 ppm, 13 weeks
PARAFFIN OIL (CAS 8012-95-1)		
Acute		
Oral		
LD50	Mouse	22 g/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 mg/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

Corrosivity

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

Irritation Corrosion - Skin

ISOPROPYL ALCOHOL	Acute dermal irritation; OECD 404 Result: Non-irritant Notes: UN SIDS evaluation: 2-Propanol

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

Eye

BETAMETHASONE VALERATE	0.1 % formulation Result: Non-Irritating Species: Rabbit
ISOPROPYL ALCOHOL	OECD 405 Result: Mild irritant Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol

Respiratory sensitization Not available.

Skin sensitization May cause sensitization by skin contact.

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.

ISOPROPYL ALCOHOL	Ames Result: Negative In vivo Micronucleus Result: Negative Species: Mouse SA7 - Sister Chromatid Exchange Result: Negative
BETAMETHASONE VALERATE	SAR / QSAR, Corticosteroids regarded as minimal risk for genotoxicity Result: Negative
ISOPROPYL ALCOHOL	Sister Chromatid Exchange, V79 cells Result: Negative mammalian cell mutation assay (CHO/HGPRT forward mutation assay) Result: Negative

Carcinogenicity Not classifiable as to carcinogenicity to humans. Paraffin oil is listed 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.

ISOPROPYL ALCOHOL	2 year bioassay, Inhalation study Result: Negative Species: Rat Notes: UN SIDS evaluation: 2-Propanol Inhalation study Result: Negative Species: Mouse Notes: UN SIDS evaluation: 2-Propanol

US. National Toxicology Program (NTP) Report on Carcinogens

PARAFFIN OIL (CAS 8012-95-1)	Known To Be Human Carcinogen.

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

ISOPROPYL ALCOHOL	< 1200 mg/kg/day Embryo-foetal development, Developmental neurotoxicity Result: Foetal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol < 240 mg/kg/day Epidemiology Result: Maternal NOAEL Species: Human < 400 mg/kg/day Embryo-foetal development Result: Maternal NOAEL Species: Rabbit Notes: UN SIDS evaluation: 2-Propanol

ISOPROPYL ALCOHOL	< 480 mg/kg/day Epidemiology Result: Foetal NOAEL Species: Human < 500 mg/kg/day Two generation study Result: Maternal toxicity; adverse effects on offspring. Species: Rat Notes: UN SIDS evaluation: 2-Propanol
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.

ISOPROPYL ALCOHOL	Result: Narcosis Organ: Central Nervous System.

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

Aspiration hazard Not likely, due to the form of the product.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Toxic to aquatic life. No information is available about the potential of this material to produce adverse environmental effects.

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
ISOPROPYL ALCOHOL (CAS 67-63-0)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Industrial sludge	> 1000 mg/l, 3 hours
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 1000 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	13299 mg/l, 48 hours, Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	> 1400 mg/l, 96 hours, Static test
		Fathead minnow (Juvenile Pimephales promelas)	6550 - 10400 mg/l, 96 hours, Flow-through test
		Mosquito fish (Juvenile Gambusia affinis)	> 1400 mg/l, 96 hours, Static test
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	161 mg/l, 72 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	2031 mg/l, 96 hours, Static test
		Golden ide/orfe (Adult Leuciscus idus)	590 - 1018 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	18.8 mg/l, 15 minutes

Components		Species	Test Results
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours, Static test

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

ISOPROPYL ALCOHOL	3.1 - 14.5 Days Measured

Hydrolysis

Half-life (Hydrolysis-neutral)

BETAMETHASONE VALERATE	6.5 Days Measured, pH 7 Buffer Solution

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

GLYCERIN	-1.76
ISOPROPYL ALCOHOL	0.26
BETAMETHASONE VALERATE	3.6 (Measured).

Mobility in soil

Mobility in general

Volatility

Henry's law

ISOPROPYL ALCOHOL	0.000008 atm m^3/mol Measured, 25 °C

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

UN number	UN1993
UN proper shipping name	Flammable liquids, n.o.s. (BETNOVATE LOTION (CONTAINING ISOPROPYL ALCOHOL)), MARINE POLLUTANT
Transport hazard class(es)	3
Subsidiary class(es)	Not available.
Packing group	III
Special precautions for user	Not available.
Labels required	3
Special provisions	B1, B52, IB3, T4, TP1, TP29
Packaging exceptions	150
Packaging non bulk	203
Packaging bulk	242

IATA

UN number	UN1993
UN proper shipping name	Flammable liquid, n.o.s. (BETNOVATE LOTION (CONTAINING ISOPROPYL ALCOHOL))
Transport hazard class(es)	3
Subsidiary class(es)	-
Packaging group	III

Environmental hazards	No
Labels required	Not available.
ERG Code	3L
Special precautions for user	Not available.

IMDG

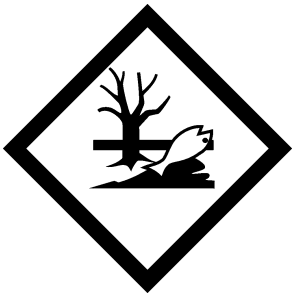
UN number	UN1993
UN proper shipping name	FLAMMABLE LIQUID, N.O.S. (BETNOVATE LOTION (CONTAINING ISOPROPYL ALCOHOL))
Transport hazard class(es)	3
Subsidiary class(es)	-
Packaging group	III
Environmental hazards	
Marine pollutant	Yes
Labels required	Not available.
EmS	F-E, S-E
Special precautions for user	Not available.

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.

DOT

IATA; IMDG

Marine pollutant



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)

ISOPROPYL ALCOHOL (CAS 67-63-0) 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 - Yes 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

GLYCERIN (CAS 56-81-5)
ISOPROPYL ALCOHOL (CAS 67-63-0)
PARAFFIN OIL (CAS 8012-95-1)

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

ISOPROPYL ALCOHOL (CAS 67-63-0)	500 lbs

US. Pennsylvania RTK - Hazardous Substances

GLYCERIN (CAS 56-81-5)
ISOPROPYL ALCOHOL (CAS 67-63-0)
PARAFFIN OIL (CAS 8012-95-1)

US. Rhode Island RTK

ISOPROPYL ALCOHOL (CAS 67-63-0)

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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)	Yes
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	Yes
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	08-19-2013
Revision date	08-19-2013
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
Physical & Chemical Properties: Multiple Properties
Transport Information: Proper Shipping Name/Packing Group
GHS: Classification