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 LOTION
Registration number	-
Synonyms	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)
Issue date	19-August-2013
Version number	09
Revision date	19-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 Contains METHYL PARABEN. May produce an allergic reaction.

2.3. Other hazards None known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
PARAFFIN OIL	10 - < 20	8012-95-1 232-384-2	-	-	
Classification: **DSD:** Xi;R36					
CLP: Eye Irrit. 2;H319					
Isopropyl alcohol	10.2	67-63-0 200-661-7	-	603-117-00-0	
Classification: **DSD:** F;R11, Xi;R36, R67					
CLP: Flam. Liq. 2;H225, Eye Irrit. 2;H319, STOT SE 3;H336					
GLYCERIN	5 - < 10	56-81-5 200-289-5	-	-	
Classification: **DSD:** -					
CLP: -					
XANTHAN GUM	< 1	11138-66-2 234-394-2	-	-	
Classification: **DSD:** -					
CLP: -					
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					
METHYL PARABEN	< 0.2	99-76-3 202-785-7	-	-	
Classification: **DSD:** Xi;R36, R43					
CLP: Skin Sens. 1;H317, Eye Irrit. 2;H319					
Other components below reportable levels	70 - < 80				

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

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. 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 centre immediately.

4.2. Most important symptoms and effects, both 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).

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Flammable liquid and vapour.

5.1. Extinguishing media

Suitable extinguishing media Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture Vapours may form explosive mixtures with air. By heating and fire, harmful vapours/gases may be formed. Vapours may travel considerable distance to a source of ignition and flash back. 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. 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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. 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.

For emergency responders Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.

6.2. 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.

6.3. Methods and material 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 product from entering drains. 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 Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Do not smoke. 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. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe storage, including any incompatibilities 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).

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	Reproductive hazard
		4	Skin
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Isopropyl alcohol (CAS 67-63-0)	STEL	1250 mg/m3	
		500 ppm	
	TWA	999 mg/m3	
		400 ppm	

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.

Individual protection measures, such as personal protective equipment

General information Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Eye wash fountain is recommended. Wear approved safety glasses with side shields if eye contact is possible. (eg. EN 166)

Skin protection

- 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. No personal respiratory protective equipment normally required. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Not available.

Hygiene measures Handle in accordance with good industrial hygiene and safety practices. 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 Lotion.

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	39 - 40 °C (102.2 - 104 °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	Strong oxidising agents.
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. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents. Isocyanates Acids. Chlorine.
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	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	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).

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
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
METHYL PARABEN (CAS 99-76-3)		
Acute		
Oral		
LD50	Mouse	> 8 g/kg
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 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 sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation May cause sensitisation by skin contact.

Sensitisation

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.

Germ cell mutagenicity

Mutagenicity

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

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

Reproductive toxicity

Reproductivity

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 < 480 mg/kg/day Epidemiology Result: Foetal NOAEL Species: Human

Reproductivity

ISOPROPYL ALCOHOL	< 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.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity 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
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.

12.2. Persistence and degradability

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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

BETAMETHASONE VALERATE	28 %, 28 days Modified MITI (II) Test., Activated sludge
Isopropyl alcohol	99.9 %, 28 days Coupled Unit test (OECD 303A), Activated sludge

Percent degradation (Aerobic biodegradation-ready)

Isopropyl alcohol	95 %, 20 Days Batch activated sludge (BAS), Activated sludge

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

BETAMETHASONE VALERATE	3.6 (Measured).
GLYCERIN	-1.76
Isopropyl alcohol	0.26
METHYL PARABEN	1.96

12.4. Mobility in soil

Mobility in general

Volatility

Henry's law

Isopropyl alcohol	0.000008 atm m^3/mol Measured, 25 °C

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. 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.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN1993
14.2. UN proper shipping name	Flammable liquids, n.o.s. (BETNOVATE LOTION (CONTAINING ISOPROPYL ALCOHOL))
14.3. Transport hazard class(es)	3
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	Yes
Tunnel restriction code	Not available.
Labels required	3
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	UN1993
14.2. UN proper shipping name	Flammable liquid, n.o.s. (BETNOVATE LOTION (CONTAINING ISOPROPYL ALCOHOL))
14.3. Transport hazard class(es)	3
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	Not available.
Labels required	Not available.
ERG code	3L
14.6. Special precautions for user	Not available.

IMDG

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

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.

ADR; IATA; IMDG

Marine pollutant

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

Isopropyl alcohol (CAS 67-63-0)

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

Not listed.

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

Not listed.

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

Isopropyl alcohol (CAS 67-63-0)

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

Not listed.

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	R10 Flammable. R11 Highly flammable. R36 Irritating to eyes. 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. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. 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. R67 Vapours may cause drowsiness and dizziness. H225 Highly flammable liquid and vapour. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. 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
Physical & Chemical Properties:
Transport Information: Product Shipping Name/Packing Group
GHS: Classification

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.