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	SEPTRIN FOR INFUSION
Registration number	-
Synonyms	SEPTRIN INJECTION AMPOULE 400/80 MG/5 ML * SEPTRIN I.V * SEPTRIN I.V SOLUCAO PARA PERFUSAO INTRAVENOSA * SEPTRIN IM INJECTION * SEPTRIN INFUSION * SEPTRIN INJECTION * SEPTRIN IV AMPOULS * SEPTRIN IV INFUSION * SEPTRIN IV INJECTION * SEPTRIN ROZTWOR DO INIEKEJI 480 MG/5 ML * SEPTRIN SOLUCION INFUSION I.V 5 ML * EUSAPRIM INFUSION * SULPHAMETHOXAZOLE AND TRIMETHOPRIM, FORMULATED PRODUCT
Issue date	09-December-2014
Version number	07
Revision date	09-December-2014

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.

2.3. Other hazards

Flammable liquid and vapour.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Propylene glycol	< 50	57-55-6 200-338-0	-	-	
Classification: **DSD:** -					
CLP: -					
ETHYL ALCOHOL, 90-99%	< 15	64-17-5 200-578-6	-	603-002-00-5	
Classification: **DSD:** F;R11, Xi;R36					
CLP: Flam. Liq. 2;H225, Eye Irrit. 2;H319, Carc. 1A;H350					
SULFAMETHOXAZOLE	< 10	723-46-6 211-963-3	-	-	
Classification: **DSD:** R52/53					
CLP: Aquatic Chronic 2;H411					
TRIMETHOPRIM	2	738-70-5 212-006-2	-	-	
Classification: **DSD:** Xn;R22					
CLP: Acute Tox. 4;H302					
SODIUM HYDROXIDE	< 2	1310-73-2 215-185-5	-	011-002-00-6	
Classification: **DSD:** C;R35					
CLP: Acute Tox. 3;H301, Acute Tox. 4;H312, Skin Corr. 1A;H314					

Other components below reportable levels < 30

List of abbreviations and symbols that may be used above

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 In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed Accidental exposure or contact might produce: nausea, fever, diarrhoea.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards Flammable liquid and vapour.

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 Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. 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.

For emergency responders Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

6.3. Methods and material for containment and cleaning up Keep combustibles (wood, paper, oil etc) away from spilled material.

Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapours or divert vapour cloud drift. 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: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

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

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. When using do not smoke. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Avoid release to the environment. No special control measures required for the normal handling of this product.

7.2. Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

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
SULFAMETHOXAZOLE (CAS 723-46-6)	8 HR TWA	2000 mcg/m3	
	OHC	1	
TRIMETHOPRIM (CAS 738-70-5)	8 HR TWA	500 mcg/m3	
	OHC	2	
TRIS(HYDROXYMETHYL)AMINOMETHANE (CAS 77-86-1)	OHC	1	PROVISIONAL

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.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls	General ventilation normally adequate. 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	If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.
Skin protection	
- Hand protection	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Not normally needed.
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Aqueous solution.
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	44 - 45 °C (111,2 - 113 °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)

Solubility (water)	Not available.
Solubility (other)	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 acids.
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. Peroxides. Phenols.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use.
Symptoms	Accidental exposure or contact might produce: nausea, fever, diarrhoea.

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. Health injuries are not known or expected under normal use.

Components	Species	Test results
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
SODIUM HYDROXIDE (CAS 1310-73-2)		
Acute		
Dermal		
LD50	Rabbit	1350 mg/kg
Oral		
LD50	Rat	104 - 340 mg/kg
SULFAMETHOXAZOLE (CAS 723-46-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
TRIMETHOPRIM (CAS 738-70-5)		
Acute		
Oral		
LD50	Rat	1360 mg/kg

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

Skin corrosion/irritation Health injuries are not known or expected under normal use. May be irritating to the skin.

Corrosivity

SULFAMETHOXAZOLE	Acute dermal irritation Result: negative Species: Rabbit

Irritation Corrosion - Skin

TRIMETHOPRIM	Acute dermal irritation Result: negative Species: Rabbit

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. May be irritating to eyes.

Eye

SULFAMETHOXAZOLE	Acute ocular irritation Result: negative Species: Rabbit

Respiratory sensitisation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin sensitisation Health injuries are not known or expected under normal use.

Sensitisation

SULFAMETHOXAZOLE	Maximisation assay (Magnusson and Kligman) Result: negative Species: Guinea pig
TRIMETHOPRIM	Maximisation assay (Magnusson and Kligman) Result: negative Species: Guinea pig

Germ cell mutagenicity Health injuries are not known or expected under normal use.

Mutagenicity

SULFAMETHOXAZOLE	Ames Assay, GLP assay Result: negative
TRIMETHOPRIM	Ames Assay, GLP assay; Literature data Result: negative
	Chromosomal Aberration Assay In Vitro, CHO cells, Literature data Result: Equivocal (chromosome damage)
SULFAMETHOXAZOLE	Chromosomal Aberration Assay In Vitro, human peripheral lymphocytes Result: negative
TRIMETHOPRIM	Chromosomal Aberration Assay In Vitro, human peripheral lymphocytes, Literature data Result: negative
SULFAMETHOXAZOLE	Micronucleus Assay in vitro, cultured human peripheral lymphocytes Result: positive
TRIMETHOPRIM	Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive
SULFAMETHOXAZOLE	Syrian Hamster Embryo (SHE) cell transformation assay Result: positive

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

SULFAMETHOXAZOLE	2 year bioassay Result: Positive (thyroid tumours) Species: Rat
TRIMETHOPRIM	SAR / QSAR, DEREK, Lhasa, UK Result: No structual alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

SULFAMETHOXAZOLE (CAS 723-46-6)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Health injuries are not known or expected under normal use. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

TRIMETHOPRIM	Embryo-foetal development - Oral, Literature data Result: Teratogenic and embryotoxic; folic acid antagonist; adverse effects noted at oral doses 40X equivalent of therapeutic dose Species: Rat Embryo-foetal development - Oral, Literature data Result: Teratogenic and embryotoxic; folic acid antagonist; adverse effects noted at oral doses 6X equivalent of therapeutic dose Species: Rabbit

Reproductivity

TRIMETHOPRIM — Fertility, Literature data
Result: NOAEL / fertility = 70 mg/kg/day (male) and 14 mg/kg/day (female) (maximum doses)
Species: Rat

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard No studies have been conducted.

Mixture versus substance information No information available.

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

SECTION 12: Ecological information

12.1. Toxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test results
Propylene glycol (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM HYDROXIDE (CAS 1310-73-2)			
Aquatic			
Acute			
Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	45,4 mg/l, 96 hours Static test
SULFAMETHOXAZOLE (CAS 723-46-6)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours Nominal, OECD 209
Algae	EC50	Blue-green algae (S. leopolensis)	0,0268 mg/l, 96 hours Measured
	NOEC	Blue-green algae (S. leopolensis)	0,0059 mg/l
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	15,51 mg/l, 48 hours OECD 202
		Water flea (Daphnia magna)	> 100 mg/l, 48 hours , OECD 202
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 1000 mg/l
	NOEC	Zebra fish (Adult Brachydanio rerio)	> 8 mg/l, 10 days

Components		Species	Test results
Chronic			
Crustacea	NOEC	Water flea (Ceriodaphnia dubia)	0,25 mg/l, 7 days 7 day static renewal, EPA 1002 Method
TRIMETHOPRIM (CAS 738-70-5)			
Acute			
	IC50	Activated sludge	17,8 mg/l
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	110 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	123 mg/l, 48 hours
Fish	NOEC	Zebra fish (Adult Brachydanio rerio)	100 mg/l, 72 hours
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 7 days 7 day static renewal
	NOEC	Water flea (Ceriodaphnia dubia)	5,6 mg/l, 7 days

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

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

Propylene glycol	1,3 - 2,3 years Estimated
SULFAMETHOXAZOLE	2,4 Days Measured

Half-life (Photolysis-atmospheric)

Propylene glycol	32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

Propylene glycol	62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge
SULFAMETHOXAZOLE	0 %, 28 days Zahn-Wellens 44 %, 13 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
TRIMETHOPRIM	50 %, 42 days, Activated sludge 50 %, 75 days, Sediment

Percent degradation (Anaerobic biodegradation)

Propylene glycol	100 %, 9 days
TRIMETHOPRIM	50 %, 100 days, Sediment

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow)

ETHYL ALCOHOL, 90-99%	-0,31
Propylene glycol	-1,35
SULFAMETHOXAZOLE	0,68
TRIMETHOPRIM	0,91 0,96

Bioconcentration factor (BCF)

Propylene glycol	< 1 Estimated
TRIMETHOPRIM	3 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

SULFAMETHOXAZOLE	0,01 Measured, pH 7
TRIMETHOPRIM	1,88 Measured

Soil/sediment sorption - log Koc

TRIMETHOPRIM	1,88 Estimated

Mobility in general

Volatility

Henry's law

Propylene glycol	0 atm m^3/mol Estimated
SULFAMETHOXAZOLE	0 atm m^3/mol, 25 C Estimated
TRIMETHOPRIM	0 atm m^3/mol Estimated

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). Avoid discharge into water courses or onto the ground.
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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN1170
14.2. UN proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Hazard No. (ADR)	30
Tunnel code	D/E
14.4. Packing group	III
14.5. Environmental hazards	No.
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	UN1170
14.2. UN proper shipping name	Ethanol solution
14.3. Transport hazard class(es)	3
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No.
Labels required	3
ERG Code	3L
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed.
Additional Information:	
Passenger & cargo	Allowed.

IMDG

14.1. UN number	UN1170
14.2. UN proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	No.
EmS	F-E, S-D

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

General information Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

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(10) 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

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

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

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

SODIUM HYDROXIDE (CAS 1310-73-2)

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

SODIUM HYDROXIDE (CAS 1310-73-2)

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. R22 Harmful if swallowed. R35 Causes severe burns. R36 Irritating to eyes. R36/38 Irritating to eyes and skin. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H225 Highly flammable liquid and vapour. H301 Toxic if swallowed. H302 Harmful if swallowed. H312 Harmful in contact with skin. H314 Causes severe skin burns and eye damage. H319 Causes serious eye irritation. H350 May cause cancer. H411 Toxic to aquatic life with long lasting effects.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Ecological Information: Ecotoxicity Transport Information: Material Transportation Information Regulatory Information: Risk Phrases - Class. 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.