SAFETY DATA SHEET

1. Identification

Product identifier **SEPTRIN FOR INFUSION**

Other means of identification

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

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

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL * 1,2-DIHYDROXYPROPANE * 2-HYDROXYPROPANOL * ISOPROPYLENE GLYCOL * METHYLETHYLENE GLYCOL * METHYLETHYL GLYCOL * MONOPROPYLENE GLYCOL * 2,3-PROPANEDIOL * ALPHA-PROPYLENE GLYCOL * 1,2-PROPYLENE GLYCOL * (RS)-1,2-PROPANEDIOL * 1,2-(RS)-PROPANEDIOL * 1,2-PROPANDIOL * DL-1,2-PROPANEDIOL * DL-PROPYLENE GLYCOL * PROPANE-1,2-DIOL (PROPYLENE GLYCOL) * PROPANE-1-2-DIOL * PROPANEDIOL,1,2-	57-55-6	< 50
ETHYL ALCOHOL, 90-99%	ETHANOL (ALCOHOL BP 96%) * PLAIN BRITISH SPIRIT (95%) * DOUBLY RECTIFIED SPIRIT (96%) * ETHANOL (95% GL) * U 2273 * RM 20 * ETHYL ALCOHOL, 96% V/V * HUNGARIAN ALCOHOL 96% V/V * U 1139 * ETHANOL B.P., DRS * U 1109 * ETHANOL DRAA * ETHANOL DRS	64-17-5	< 15
SULFAMETHOXAZOLE	CCI11971 * N-(5-METHYLISOXAZOL-3-YL) SULPHANILAMIDE * 4-AMINO-N-(5-METHYL-3-ISOXAZOLYL) BENZENESULPHONAMIDE * SULPHAMETHOXAZOLE * 1689 (GW ACN) * GW296858X * CCI11974	723-46-6	< 10
TRIMETHOPRIM	CCI 2095 * 5-((3,4,5-TRIMETHOXYPHENYL)METHYL)-2,4-PYRIMIDINEDIAM INE * TRIMETHOXYPRIM * TMP * 1690 (GW ACN)	738-70-5	2
SODIUM HYDROXIDE	CAUSTIC SODA * SODIUM HYDRATE	1310-73-2	< 2
TRIS(HYDROXYMETHYL)AMINOMETHANE	2-AMINO-2-(HYDROXYMETHYL)-1,3-PROPANEDIOL * AMINOTRIMETHYLOLMETHANE * AMINOTRIS(HYDROXYMETHYL)METHANE * TRIS (BUFFERING AGENT) * 2-AMINO-2-HYDROXYMETHYL-1,3-PROPANEDIOL * TROMETAMOL	77-86-1	< 2
SODIUM METABISULFITE	DISULFUROUS ACID, DISODIUM SALT * DISODIUM DISULPHITE * DISODIUM DISULFITE * DISODIUM METABISULFITE * DISODIUM PYROSULFITE * DISULFUROUS ACID DISODIUM SALT * PYROSULFUROUS ACID, DISODIUM SALT * SODIUM DISULFITE (NA2S2O5) * SODIUM PYROSULFITE * SODIUM DISULFITE	7681-57-4	< 1
Other components below reportable levels			< 30

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

4. 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 center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed	Accidental exposure or contact might produce: nausea, fever, diarrhoea.
Indication of 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 center.
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.

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	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.
General fire hazards	Flammable liquid and vapor.

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 SDS.
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. Use water spray to reduce vapors or divert vapor 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. For waste disposal, see section 13 of the SDS.
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.

7. Handling and storage

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.
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).

8. Exposure controls/personal protection

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

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

Components	Type	Value
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	PEL	1900 mg/m3
		1000 ppm
SODIUM HYDROXIDE (CAS 1310-73-2)	PEL	2 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	STEL	1000 ppm
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3
SODIUM METABISULFITE (CAS 7681-57-4)	TWA	5 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	TWA	1900 mg/m3
		1000 ppm
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3
SODIUM METABISULFITE (CAS 7681-57-4)	TWA	5 mg/m3

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

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

Exposure guidelines

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

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves.

Other Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Aqueous solution.
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	111.2 - 113 °F (44 - 45 °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)	
Solubility (water)	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. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Peroxides. Phenols.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics Accidental exposure or contact might produce: nausea, fever, diarrhoea.

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 or skin sensitization

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

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

Sensitization

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

Mutagenicity

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

SODIUM METABISULFITE (CAS 7681-57-4)	3 Not classifiable as to carcinogenicity to humans.
SULFAMETHOXAZOLE (CAS 723-46-6)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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
	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.

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

12. Ecological information

Ecotoxicity 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
SODIUM METABISULFITE (CAS 7681-57-4)			
Chronic			
Other	LC50	Pseudomonas putida	56 mg/l, 17 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	40 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	89 mg/l, 24 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	32 mg/l, 96 hours
		Rainbow trout (Adult Oncorhyncus mykiss)	100 - 200 mg/l, 96 hours
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.

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

Bioaccumulative potential

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

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

Volatility

Henry's law

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

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

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). 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.

14. Transport information

DOT

UN number UN1170
UN proper shipping name Ethanol solutions or Ethyl alcohol solutions
Transport hazard class(es)
Class 3
Subsidiary risk -
Label(s) 3
Packing group III
Special precautions for user Not available.
Special provisions 24, B1, IB3, T2, TP1
Packaging exceptions 4b, 150
Packaging non bulk 203
Packaging bulk 242

IATA

UN number UN1170
UN proper shipping name Ethanol solution
Transport hazard class(es) 3
Subsidiary class(es) -
Packaging group III
Environmental hazards No.
Labels required 3
ERG Code 3L
Special precautions for user Not available.
Other information
Cargo aircraft only Allowed.
Passenger & cargo Allowed.

IMDG

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

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.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	Listed.
SODIUM HYDROXIDE (CAS 1310-73-2)	Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

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.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)
SODIUM HYDROXIDE (CAS 1310-73-2)
SODIUM METABISULFITE (CAS 7681-57-4)

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

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)
PROPYLENE GLYCOL (CAS 57-55-6)
SODIUM HYDROXIDE (CAS 1310-73-2)
SODIUM METABISULFITE (CAS 7681-57-4)

US. Pennsylvania Worker and Community Right-to-Know Law

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)
PROPYLENE GLYCOL (CAS 57-55-6)
SODIUM HYDROXIDE (CAS 1310-73-2)
SODIUM METABISULFITE (CAS 7681-57-4)

US. Rhode Island RTK

SODIUM HYDROXIDE (CAS 1310-73-2)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

ETHYL ALCOHOL, 90-99% (CAS 64-17-5) Listed: April 29, 2011
Listed: July 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

ETHYL ALCOHOL, 90-99% (CAS 64-17-5) Listed: October 1, 1987

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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
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 12-09-2014

Revision date 12-09-2014

Version # 07

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings	Health: 2 Flammability: 3 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 3 Instability: 0
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: Undisclosed Ingredient Statement Physical & Chemical Properties: Ecological Information: Ecotoxicity Transport Information: Proper Shipping Name/Packing Group Regulatory Information: Risk Phrases - Class. GHS: Classification