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	NEOSPORIN EYE/EAR DROPS
Registration number	-
Synonyms	NEOSPORIN EAR/EYE SOLUTION * GRAMICIDIN, NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE, FORMULATED PRODUCT
Issue date	12-December-2014
Version number	04
Revision date	12-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

This product is non-flammable.
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
ETHANOL	0,5	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					
NEOMYCIN SULFATE	<1,0	1405-10-3 215-773-1	-	-	
Classification: **DSD:** Xi;R36, R43					
CLP: Skin Sens. 1;H317, Eye Irrit. 2;H319					
POLYMYXIN B SULFATE	<1,0	1405-20-5 2157747	-	-	
Classification: **DSD:** Xn;R22					
CLP: Acute Tox. 4;H302					
Propylene glycol	< 1	57-55-6 200-338-0	-	-	
Classification: **DSD:** -					
CLP: -					
BENZALKONIUM CHLORIDE	<0,1	8001-54-5 -	-	-	M=10
Classification: **DSD:** C;R34, Xn;R22, N;R50/53					
CLP: Acute Tox. 4;H302, Skin Corr. 1B;H314, Aquatic Acute 1;H400, Aquatic Chronic 1;H410					
GRAMICIDIN	<0,1	1405-97-6 215-790-4	-	-	
Classification: **DSD:** -					
CLP: -					
Other components below reportable levels	>95,0				

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 Direct contact with eyes may cause temporary irritation.

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 This product is non-flammable.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

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 upwind. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. 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 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 Avoid prolonged exposure. Observe good industrial hygiene practices. No special control measures required for the normal handling of this product.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. 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
GRAMICIDIN (CAS 1405-97-6)	OHC	2	
NEOMYCIN SULFATE (CAS 1405-10-3)	8 HR TWA	2000 mcg/m3	
	OHC	1	SKIN SENSITISER
		1	Reproductive hazard
POLYMYXIN B SULFATE (CAS 1405-20-5)	8 HR TWA	100 mcg/m3	
	OHC	3	

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	Not available.

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	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	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	Expected to be non-flammable based on components present.
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	The product is stable and non-reactive under normal conditions of use, storage and transport.
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	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. 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.

NEOMYCIN SULFATE — Literature search
Result: May cause irritation

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. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test results
BENZALKONIUM CHLORIDE (CAS 8001-54-5)		
Acute		
Oral		
LD50	Rat	240 - 590 mg/kg
ETHANOL (CAS 64-17-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Chronic		
Oral		
LOAEL	Monkey	40 %, 48 months % ingested calories
Subacute		
Oral		
LOEL	Rat	16,9 g/kg, 4 weeks Dietary - Dose given as g/kg/day
		6 %, 4 weeks percent in diet - continuous
Subchronic		
Inhalation		
LOEL	Rat	2 ml, 36 weeks haematological parameters
NOAEL	Guinea pig	3000 ppm No adverse effects
	Rat	86 mg/m3, 90 Day Daily dosing

Components	Species	Test results
Oral		
LOAEL	Rat	5000 mg/kg/day, 10 weeks Liver toxicity
		80 ml/kg, 85 Day Daily dose - Liver toxicity
		10,2 g/kg, 12 weeks Dosed in drinking water - Continuous
		7,7 g/kg, 12 weeks Dosed in drinking water - continuous
GRAMICIDIN (CAS 1405-97-6)		
Acute		
Oral		
Evident toxicity	Rat	> 1000 mg/kg
LD	Rat	> 1000 mg/kg
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
Oral		
LD50	Mouse	> 8000 mg/kg
POLYMYXIN B SULFATE (CAS 1405-20-5)		
Acute		
Oral		
LD50	Mouse	790 mg/kg

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. Health injuries are not known or expected under normal use.

Corrosivity

NEOMYCIN SULFATE	Literature search Result: Irritant
POLYMYXIN B SULFATE	Literature search Result: May cause irritation
ETHANOL	OECD 404 Result: Negative; not considered a significant irritant Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

POLYMYXIN B SULFATE	Acute ocular irritation Result: Non-Irritating Species: Rabbit
NEOMYCIN SULFATE	Literature search Result: Irritant
GRAMICIDIN	Literature search Result: Severe Irritant
ETHANOL	OECD 405 Result: Severe Species: Rabbit

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

NEOMYCIN SULFATE	Literature search Result: positive

Skin sensitisation This product is not expected to cause skin sensitisation. Health injuries are not known or expected under normal use.

Sensitisation

POLYMYXIN B SULFATE	Clinical use Result: Hypersensitvity reactions can occur rarely in patients.
GRAMICIDIN	Literature search Result: Sensitisation may occur in susceptible individuals
NEOMYCIN SULFATE	Literature search Result: positive
ETHANOL	OECD 406 Result: negative Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Health injuries are not known or expected under normal use.

Mutagenicity

ETHANOL	Ames Result: negative Chromosomal Aberration Assay In Vitro, CHO cells Result: negative Dominant lethal assay Result: positive Species: Mouse Dominant lethal assay Result: positive Species: Rat Gene mutation and repair Result: negative Species: Bacteria Gene mutation and repair Result: positive Species: Bacteria In vitro cytogenetics assay Result: positive In vitro cytogenetics assay Result: positive Species: Aspergillus niger L5178Y mouse lymphoma thymidine kinase locus assay Result: Weakly positive Yeast mutation Result: negative Yeast mutation Result: positive in vitro micronucleus assay Result: negative in vivo cytogenetics assay Result: negative Species: Hamster in vivo cytogenetics assay Result: negative Species: Rat in vivo cytogenetics assay Result: positive Species: Mouse sister chromatid exchange Result: positive

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Contains a material (ethanol) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.

ETHANOL	0, inadequate study Result: Increase in liver sarcomas Species: Mouse 0, inadequate study Result: Time to tumour reduced Species: Mouse Test Duration: 80 weeks 0, inadequate study Result: negative Species: Hamster Test Duration: 807 Day 0, inadequate study Result: negative Species: Mouse Test Duration: 1020 Day 0, inadequate study Result: negative Species: Rat 0, inadequate study Result: negative Species: Rat Test Duration: 78 weeks
NEOMYCIN SULFATE	25 mg/kg/day, Auditory toxicity, no evidence of carcinogenicity. Species: Rat Observation Period: 104 weeks
ETHANOL	Epidemiology, causation linked to excessive consumption. Species: Human Organ: oral cavity, larynx, pharynx, oesophagus, liver

Carcinogenicity

ETHANOL	Neonatal, inadequate study Result: negative Species: Rat

Reproductive toxicity This product is not expected to cause reproductive or developmental effects. Health injuries are not known or expected under normal use.

Reproductivity

ETHANOL	0,3 - 4,1 g/kg Embryo-foetal development - Oral, daily dose Species: Monkey Organ: facial anomolies, nervous system dysfunction 1 - 2 g/kg Embryo-foetal development - Oral, daily dose Result: embryolethality Species: Rat 1,8 g/kg Embryo-foetal development - Oral, daily dose Result: Increased abortion Species: Monkey
NEOMYCIN SULFATE	25 mg/kg/day 3-generation study, Dietary study. Result: NOAEL (maximum dose) Species: Rat
ETHANOL	5 g/kg Embryo-foetal development - Oral, daily dose - intravenous Result: reduced foetal body weight; no malformations or other variations Species: Monkey 7 - 17 g/kg Embryo-foetal development - Oral, daily dose - gavage Species: Rat Organ: skeletal malformations, dilated renal pelves Embryo-foetal development - Oral, 15-30% in diet Result: resorptions, neural defects, cardiac malformations Species: Mouse Embryo-foetal development - Oral, Causation is linked to excessive consumption. Species: Human Organ: growth deficiency, CNS dysfunction, facial defects, major organ malformation Embryofetal Development, in utero - 36% total calories Species: Rat Organ: gonadal growth and development Fertility, Female, 10% in drinking water Result: negative Species: Rat Fertility, Female, 20-25% total calories Result: negative Species: Rat Fertility, Male, 5-6% v/v liquid diet Species: Mouse Organ: significant effects on testes and seminal vesicles Test Duration: 70 Day

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

GRAMICIDIN	Animal Studies Organ: Red blood cells.
POLYMYXIN B SULFATE	Clinical use Result: High doses can cause respiratory irritation. Organ: Lungs

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

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 Not expected to be harmful to aquatic organisms.

Components		Species	Test results
BENZALKONIUM CHLORIDE (CAS 8001-54-5)			
Acute			
	IC50	Activated sludge	14 mg/l
Aquatic			
Acute			
Algae	EC50	Green algae (Chlorella pyrenoidosa)	0,056 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0,018 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	0,32 mg/l, 96 hours Static test
		Guppy (Juvenile Poecilia reticulata)	1,3 mg/l, 96 hours Static renewal test
		Orange-red killfish (Adult Oryzias latipes)	2,4 mg/l, 96 hours Static renewal test
		Rainbow trout (Adult Oncorhyncus mykiss)	1,15 mg/l, 96 hours Static test
Microtox	EC50	Microtox	1,43 mg/l, 10 minutes
ETHANOL (CAS 64-17-5)			
Aquatic			
Acute			
Algae	EC50	Blue-green algae (Microcystis aeruginosa)	1450 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	9190 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	14200 mg/l, 96 hours Flow-through test
		Rainbow trout (Adult Salmo gairdneri)	13000 mg/l, 96 hours Static test
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

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

12.2. Persistence and degradability Not available.

Photolysis

Half-life (Photolysis-aqueous)

ETHANOL	1 - 36,6 years Measured
Propylene glycol	1,3 - 2,3 years Estimated

Half-life (Photolysis-atmospheric)

ETHANOL	4 - 5,9 Days Estimated
Propylene glycol	32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ETHANOL	37 - 86 %, 5 days BOD5, Activated sludge
Propylene glycol	62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge

Percent degradation (Anaerobic biodegradation)

Propylene glycol	100 %, 9 days

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow)

ETHANOL	-0,31
Propylene glycol	-1,35

Bioconcentration factor (BCF)

Propylene glycol	< 1 Estimated

12.4. Mobility in soil Not available.

Adsorption

Soil/sediment sorption - log Koc

ETHANOL	1,2 Calculated

Mobility in general Not available.

Volatility

Henry's law

ETHANOL	0,000005 atm m3/mol Measured
Propylene glycol	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

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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.

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

ETHANOL (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

ETHANOL (CAS 64-17-5)

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	R11 Highly flammable. R22 Harmful if swallowed. R34 Causes burns. R36 Irritating to eyes. R43 May cause sensitization by skin contact. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H225 Highly flammable liquid and vapour. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H400 Very toxic to aquatic life. H410 Very 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: Transport Information: Agency Name and Packaging Type/Transport Mode Selection Regulatory Information: United States 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.