



SAFETY DATA SHEET

1. Identification

Product identifier NEOSPORIN EYE/EAR DROPS

Other means of identification

Synonyms NEOSPORIN EAR/EYE SOLUTION * GRAMICIDIN, NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE, FORMULATED PRODUCT

Recommended use of the chemical and restrictions on use

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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
ETHANOL	64-17-5	0.5
ALCOHOL ANHYDROUS		
ANHYDROUS ETHANOL		
ANHYDROUS ETHYL ALCOHOL		
ETHANOL 200 PROOF		
Ethyl alcohol		
ETHYL ALCOHOL USP 200 PROOF (USI)		
ETHYL ALCOHOL, 100%		
ETHYL HYDROXIDE		
GRAIN ALCOHOL		
ETHANOL		

NEOMYCIN SULFATE NEOMYCIN, SULFATE (SALT) NEOMYCIN SULPHATE MYCERIN SULPHATE 242 (GW ACN) MYCIGUENT NEOMIX NEOMYCIN SULFATE USP POWDER 50/50	1405-10-3	<1.0
POLYMYXIN B SULFATE GR214114X 1732 (GW ACN) AEROSPORIN POLYMYXIN B SULPHATE	1405-20-5	<1.0
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	< 1
BENZALKONIUM CHLORIDE ALKYLDIMETHYL BENZYL AMMONIUM CHLORIDE LEDA BENZALKONIUM CHLORIDE QUARTERNARY AMMONIUM COMPOUNDS, ALKYBENZYLDMETHYL, CHLORIDES ZEPHIRAN CHLORIDE ALKYL DIMETHYL BENZYLAMMONIUM CHLORIDE QUATERNARY AMMONIUM COMPOUNDS, ALKYL (C12-C16) BENZYLDMETHYL, CHLORIDES	8001-54-5	<0.1
GRAMICIDIN GRAMICIDIN D GRAMICIDINUM GR31230X GF151169X	1405-97-6	<0.1
Other components below reportable levels		>95.0

4. First-aid measures

Description of necessary 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.

Personal protection for first-aid responders 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.

Symptoms caused by exposure Direct contact with eyes may cause temporary irritation.

Medical attention and special treatment 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.

5. Fire-fighting measures

Extinguishing media

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters 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.

Hazchem Code Not available.

General fire hazards This product is non-flammable.

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

6. Accidental release measures

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.

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

Methods and materials 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. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling Observe good industrial hygiene practices. No special control measures required for the normal handling of this product.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

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/m ³	
	OHC	1	SKIN SENSITISER
		1	Reproductive hazard
POLYMYXIN B SULFATE (CAS 1405-20-5)	8 HR TWA	100 mcg/m ³	
	OHC	3	

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1880 mg/m3 1000 ppm	
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3 10 mg/m3 150 ppm	Total vapour and particulates. Particulate. Total vapour and particulates.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1880 mg/m3 1000 ppm	
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3 10 mg/m3 150 ppm	Total vapour and particulates. Particulate. Total vapour and particulates.

US. ACGIH Threshold Limit Values

Components	Type	Value
ETHANOL (CAS 64-17-5)	STEL	1000 ppm

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3 1000 ppm	
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3 10 mg/m3 150 ppm	Total vapour and particulates. Particulate. Total vapour and particulates.

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value
ETHANOL (CAS 64-17-5)	TWA	960 mg/m3 500 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Not available.
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, for example personal protective equipment (PPE)	
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	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
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.

9. 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.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour 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	Contact with incompatible materials.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on possible routes of exposure

Inhalation NEOMYCIN SULFATE	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. 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 related to exposure	Direct contact with eyes may cause temporary irritation.
Acute toxicity	Health injuries are not known or expected under normal use.

Components	Species	Test results
BENZALKONIUM CHLORIDE (CAS 8001-54-5)		
Acute		
<i>Oral</i>		
LD50	Rat	240 - 590 mg/kg
ETHANOL (CAS 64-17-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
Chronic		
<i>Oral</i>		
LOAEL	Monkey	40 %, 48 months % ingested calories
Subacute		
<i>Oral</i>		
LOEL	Rat	16.9 g/kg, 4 weeks Dietary - Dose given as g/kg/day 6 %, 4 weeks percent in diet - continuous
Subchronic		
<i>Inhalation</i>		
LOEL	Rat	2 ml, 36 weeks haematological parameters
NOAEL	Guinea pig	3000 ppm No adverse effects
	Rat	86 mg/m3, 90 Day Daily dosing
<i>Oral</i>		
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		
<i>Oral</i>		
Evident toxicity	Rat	> 1000 mg/kg
LD	Rat	> 1000 mg/kg
NEOMYCIN SULFATE (CAS 1405-10-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 8000 mg/kg
POLYMYXIN B SULFATE (CAS 1405-20-5)		
Acute		
<i>Oral</i>		
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/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 or skin sensitisation

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: Hypersensitivity 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
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Mutagenicity
ETHANOL

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
Epidemiology, causation linked to excessive consumption.
Species: Human
Organ: oral cavity, larynx, pharynx, oesophagus, liver
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.

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.

Other information

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

12. Ecological information

Ecotoxicity

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

Components		Species	Test results
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Chlorella pyrenoidosa</i>)	0.056 mg/l, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	0.018 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i>)	0.32 mg/l, 96 hours Static test
		Guppy (Juvenile <i>Poecilia reticulata</i>)	1.3 mg/l, 96 hours Static renewal test
		Orange-red killfish (Adult <i>Oryzias latipes</i>)	2.4 mg/l, 96 hours Static renewal test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	1.15 mg/l, 96 hours Static test
Microtox	EC50	Microtox	1.43 mg/l, 10 minutes
ETHANOL (CAS 64-17-5)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Blue-green algae (<i>Microcystis aeruginosa</i>)	1450 mg/l, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	9190 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Adult <i>Pimephales promelas</i>)	14200 mg/l, 96 hours Flow-through test
		Rainbow trout (Adult <i>Salmo gairdneri</i>)	13000 mg/l, 96 hours Static test
Propylene glycol (CAS 57-55-6)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Selenastrum capricornutum</i>)	19000 mg/l, 14 days
	NOEC	Green algae (<i>Selenastrum capricornutum</i>)	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 <i>Pimephales promelas</i>)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult <i>Pimephales promelas</i>)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	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.

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

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

Mobility in soil No data available for this product.

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 m³/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal methods 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.

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.

14. Transport information

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

ETHANOL (CAS 64-17-5)

Low toxicity. General: Any use

Use pattern restricts hazard. Human therapeutic use

Propylene glycol (CAS 57-55-6)

Low toxicity. General: Any use

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

BENZALKONIUM CHLORIDE (CAS 8001-54-5)

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting., If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.

For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting., If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes., If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

Australia National Pollutant Inventory (NPI): Threshold quantity

ETHANOL (CAS 64-17-5)

10 TONNES/YR Threshold Category: 1

High Volume Industrial Chemicals (HVIC)

ETHANOL (CAS 64-17-5)

10000 - 99999 TONNES See the regulation for additional information.

Propylene glycol (CAS 57-55-6)

1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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

Issue date 12-December-2014

Revision date 12-December-2014

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: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
GHS: Classification