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 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	%
ETHANOL	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	64-17-5	0.5
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

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	0.5
BENZALKONIUM CHLORIDE	ALKYLDIMETHYL BENZYL AMMONIUM CHLORIDE * LEDA BENZALKONIUM CHLORIDE * QUARTERNARY AMMONIUM COMPOUNDS, ALKYBENZYLDIMETHYL, CHLORIDES * ZEPHIRAN CHLORIDE * ALKYL DIMETHYL BENZYLAMMONIUM CHLORIDE * QUATERNARY AMMONIUM COMPOUNDS, ALKYL (C12-C16) BENZYLDIMETHYL, CHLORIDES	8001-54-5	<0.1
GRAMICIDIN	GRAMICIDIN D * GRAMICIDINUM * GR31230X * GF151169X	1405-97-6	<0.1
Other components below reportable levels			>95.0

*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
Direct contact with eyes may cause temporary irritation.

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
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 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 This product is non-flammable.

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

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.

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

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. 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/personal protection

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	

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

Components	Type	Value
ETHANOL (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
ETHANOL (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm

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 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, 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	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	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.
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	Contact with incompatible materials.
Incompatible materials	Strong oxidizing 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 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 related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation.

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
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

Components	Species	Test Results
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 or skin sensitization

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

NEOMYCIN SULFATE	Literature search Result: Positive

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

Sensitization

POLYMYXIN B SULFATE	Clinical use Result: Hypersensitvity reactions can occur rarely in patients.
NEOMYCIN SULFATE	Literature search Result: Positive
GRAMICIDIN	Literature search Result: Sensitisation may occur in susceptible individuals
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

Mutagenicity

ETHANOL	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: 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 0, inadequate study Result: Time to tumour reduced Species: Mouse Test Duration: 80 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 Neonatal, inadequate study Result: Negative Species: Rat

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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	100 mg/kg/day Embryo-foetal development, Intra-muscular administration. Result: Auditory toxicity in offspring. Species: Rat 25 mg/kg/day 3-generation study, Dietary study. Result: NOAEL (maximum dose) Species: Rat Notes: WHO Food Additive Series 25 mg/kg/day, Dietary study. Result: No adverse foetal effects observed. 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
NEOMYCIN SULFATE	Embryo-foetal development Result: No malformations. Species: Mouse Notes: Reprotox Embryo-foetal development Result: No malformations. Species: Rabbit Notes: Reprotox
ETHANOL	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.

Specific target organ toxicity - repeated exposure

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.

Chronic effects Prolonged inhalation may be harmful.

Further 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
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

Components		Species	Test Results
	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.

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 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

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

Not regulated as a dangerous good.

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

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.

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)

ETHANOL (CAS 64-17-5) 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 - No
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

ETHANOL (CAS 64-17-5)

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

ETHANOL (CAS 64-17-5)
PROPYLENE GLYCOL (CAS 57-55-6)

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

ETHANOL (CAS 64-17-5)
PROPYLENE GLYCOL (CAS 57-55-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

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

ETHANOL (CAS 64-17-5) Listed: April 29, 2011

Listed: July 1, 1988

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

ETHANOL (CAS 64-17-5)	Listed: October 1, 1987
NEOMYCIN SULFATE (CAS 1405-10-3)	Listed: October 1, 1992

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, including date of preparation or last revision

Issue date 12-12-2014

Revision date 12-12-2014

Version # 04

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

HMIS® ratings
Health: 1
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 1
Flammability: 0
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: 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