SAFETY DATA SHEET

1. Identification

Product identifier **NIGHT NURSE LIQUID**

Other means of identification

Synonyms NIGHT NURSE LIQUID (UK) * COLDREX NITE * PARACETAMOL, PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE, 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	< 20

Chemical name	Common name and synonyms	CAS number	%
POLYETHYLENE GLYCOL 300	ALPHA-HYDRO-OMEGA-HYDROXY-POLY(OXY-1,2-ETHANEDIYL) * GLYCOLS, POLYETHYLENE * CARBOWAX 300 * PEG 300 * POLY(ETHYLENE ETHER)GLYCOL * POLYETHYLENE GLYCOL * ETHYLENE GLYCOL HOMOPOLYMER * ETHYLENE GLYCOL POLYMER * RTECS TQ3630000 * POLY(OXY-1,2-ETHANEDIYL), .ALPHA.-HYDRO-.OMEGA. * POLYETHYLENEGLYCOL 6000 * POLYETHYLENGLYKOLE (PEG) (MOLMASSE 200-600)	25322-68-3	< = 15
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	< = 5
SODIUM CYCLAMATE	SODIUM CYCLOHEXANESULPHAMATE * SODIUM CYCLOHEXYL AMIDOSULPHATE * SODIUM CYCLOHEXYL SULFAMATE * SODIUM CYCLOHEXYL SULFAMIDATE * CYCLAMATE SODIUM * CYCLAMIC ACID SODIUM SALT * CYCLOHEXYL SULPHAMATE SODIUM * CYCLOHEXYL SULFAMATE SODIUM	139-05-9	< = 1
PROMETHAZINE HYDROCHLORIDE	10-(2-(DIMETHYLAMINO)PROPYL)-PHENO THIAZINE, MONOHYDROCHLORIDE * 10H-PHENOTHIAZINE-10-ETHANAMINE, N,N,ALPHA-TRIMETHYL-, MONOHYDROCHLORIDE * 173U48 HYDROCHLORIDE * 3277 R.P. * HL 8700 * N,N,ALPHA-TRIMETHYL-10H-PHENOTHIA ZINE-10-ETHANAMINE, MONOHYDROCHLORIDE * PHENOTHIAZINE, 10-(2-(DIMETHYLAMINO)PROPYL)-, MONOHYDROCHLORIDE * PROMETHAZINE HCL * RM 436 * RTECS SO8225000 * SKF-1498A	58-33-3	< 0.25
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT * BENZOATE OF SODA * SODUIM BENZOIC ACID	532-32-1	< 0.25
DEXTROMETHORPHAN HYDROBROMIDE	9ALPHA,13ALPHA,14ALPHA-MORPHINAN, 3-METHOXY-17-METHYL-, HYDROBROMIDE * DEXTROMETHORPHAN BROMIDE * METHORATE HYDROBROMIDE * C18H25NO.HBr	125-69-9	0.08
Other components below reportable levels			> 60

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

4. First-aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Take off immediately all contaminated clothing. Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If eye irritation persists: Get medical advice/attention.

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	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.
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 local poison control information centre.
General information	Take off all contaminated clothing immediately. 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. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water.
Specific hazards arising from the chemical	Vapors may form explosive mixtures with air. Vapors may travel considerable distance to a source of ignition and flash back. 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	In case of fire and/or explosion do not breathe fumes. 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. 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. Use water spray to reduce vapors or divert vapor cloud drift. 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. 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	Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. 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
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)	8 HR TWA	10 mcg/m3
	OHC	4
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)	8 HR TWA	10 mcg/m3
	OHC	4
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3
	OHC	1

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
POLYETHYLENE GLYCOL 300 (CAS 25322-68-3)	TWA	10 mg/m3	Particulate.

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

Appropriate engineering controls Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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 Chemical goggles are recommended. If contact is likely, safety glasses with side shields are recommended.

Hand protection The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Skin protection

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. When using do not smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has been developed for this material.

9. Physical and chemical properties

Appearance	
Physical state	Liquid.
Form	Liquid.
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	100.4 - 104 °F (38 - 40 °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.
Other information	
Percent volatile	56.6 % estimated

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. Alkaline metals.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational 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.

Symptoms related to the physical, chemical and toxicological characteristics Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.

Information on toxicological effects

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

Components	Species	Test Results
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)		
Acute		
Oral		
LD50	Rat	350 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
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
Other		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous

Components	Species	Test Results
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous
POLYETHYLENE GLYCOL 300 (CAS 25322-68-3)		
Acute		
Oral		
LD50	Rat	> 20 g/kg
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)		
Acute		
Oral		
LD50	Mouse	326 mg/kg
SODIUM CYCLAMATE (CAS 139-05-9)		
Acute		
Oral		
LD50	Rat	1280 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.

Corrosivity

ETHANOL	OECD 404 Result: Negative; not considered a significant irritant Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

PARACETAMOL	OECD 404, Literature data Result: Slight irritant Species: Rabbit

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Eye

ETHANOL	OECD 405 Result: Severe Species: Rabbit
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Respiratory or skin sensitization

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

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

Sensitization

ETHANOL	OECD 406 Result: Negative Species: Guinea pig
DEXTROMETHORPHAN HYDROBROMIDE	SAR, DEREK, Lhasa, UK Result: Positive

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

Mutagenicity

ETHANOL	Ames Result: Negative
DEXTROMETHORPHAN HYDROBROMIDE	Ames Result: Negative Notes: Global Safety Datasheet.
PARACETAMOL	Ames, Literature data Result: Negative
ETHANOL	Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative
PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: Positive

Mutagenicity

ETHANOL	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
PARACETAMOL	HPRT gene mutation in human lymphocytes, Literature data Result: Negative
DEXTROMETHORPHAN HYDROBROMIDE	In vitro cytogenetics assay Result: Negative Notes: Aardema A et al, Reg Tox Pharm.
ETHANOL	In vitro cytogenetics assay Result: Positive In vitro cytogenetics assay Result: Positive Species: Aspergillus niger
PARACETAMOL	In vivo Micronucleus, Literature data Result: Negative Species: Mouse
ETHANOL	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 Health injuries are not known or expected under normal use.

ETHANOL	Epidemiology, causation linked to excessive consumption. Species: Human Organ: oral cavity, larynx, pharynx, oesophagus, liver
PARACETAMOL	Literature data Result: Equivocal. Increase in ademomas at toxic dose. Species: Mouse Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat Literature data Result: Negative Species: Mouse Literature data Result: Negative Species: Rat
ETHANOL	Neonatal, inadequate study Result: Negative Species: Rat inadequate study Result: Increase in liver sarcomas Species: Mouse

Carcinogenicity

ETHANOL	inadequate study Result: Negative Species: Hamster Test Duration: 807 Day inadequate study Result: Negative Species: Mouse Test Duration: 1020 Day inadequate study Result: Negative Species: Rat inadequate study Result: Negative Species: Rat Test Duration: 78 weeks inadequate study Result: Time to tumour reduced Species: Mouse Test Duration: 80 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
SODIUM CYCLAMATE (CAS 139-05-9)	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. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

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
PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat 387 mg/kg/day Embryofetal Development, Literature data Result: Negative Species: Mouse
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
PARACETAMOL	750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weght, minor skeletal abnormalities. Species: Rat <= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
DEXTROMETHORPHAN HYDROBROMIDE	<= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rabbit Notes: Global Safety Datasheet.

Reproductivity

DEXTROMETHORPHAN HYDROBROMIDE	<= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rat Notes: Global Safety Datasheet.
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
PARACETAMOL	Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human
ETHANOL	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 May cause damage to organs by ingestion.

DEXTROMETHORPHAN HYDROBROMIDE	Organ: Central Nervous System.
PARACETAMOL	Species: Human Organ: Liver

Specific target organ toxicity - repeated exposure Causes damage to organs through prolonged or repeated exposure by ingestion.

Aspiration hazard Not likely, due to the form of the product.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)			
Aquatic			
Acute			
Algae	EC50	Algae	2.28 mg/l, 72 hours
	NOEC	Algae	0.35 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	13.78 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	< 5.51 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.66 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 100 mg/l, 3 hours
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

Components		Species	Test Results
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
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
POLYETHYLENE GLYCOL 300 (CAS 25322-68-3)			
Aquatic			
Acute			
Fish	LC50	Atlantic salmon (Salmo salar)	> 1000 mg/l, 96 hours
		Crucian carp (Carassius carassius)	> 20000 mg/l, 96 hours
		Rainbow trout,donaldson trout (Oncorhynchus mykiss)	> 20000 mg/l, 96 hours
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	1.5 mg/l, 48 hours
Fish	EC50	Fish	2 mg/l, 96 hours
SODIUM BENZOATE (CAS 532-32-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	484 mg/L, 96 hours Flow-through test

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ETHANOL	1 - 36.6 Years Measured

Half-life (Photolysis-atmospheric)

ETHANOL	4 - 5.9 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 0 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
ETHANOL	37 - 86 %, 5 days BOD5, Activated sludge
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE	93 %, 7 days Other degradation test system, Mixed Residential/Industrial

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ETHANOL	-0.31
PARACETAMOL	0.36
PROMETHAZINE HYDROCHLORIDE	-0.72
SODIUM BENZOATE	1.89

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ETHANOL	1.2 Calculated
SODIUM BENZOATE	1.16 Calculated

Mobility in general

Volatility

Henry's law

ETHANOL	0.000005 atm m3/mol Measured
PARACETAMOL	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).

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.

Read safety instructions, SDS and emergency procedures before handling.

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 - Yes
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. Massachusetts RTK - Substance List

ETHANOL (CAS 64-17-5)

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

ETHANOL (CAS 64-17-5)

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

ETHANOL (CAS 64-17-5)

US. Rhode Island RTK

Not regulated.

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

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

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
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	08-28-2014
Revision date	08-28-2014
Version #	16
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: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Toxicological Information: Transport Information: Regulatory Information: United States GHS: Classification