SAFETY DATA SHEET

1. Identification

Product identifier **BEECHAMS ALL-IN-ONE LIQUID**

Other means of identification

Synonyms BEECHAMS ALL-IN-ONE LIQUID (UK) * R&D CODE 50/56 * PARACETAMOL, GUAIPHENESIN AND PHENYLEPHRINE HYDROCHLORIDE, 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	%
D-SORBITOL	SORBITOL * L-GULITOL * 1,2,3,4,5,6-HEXANEHEXOL * D-SORBOL	50-70-4	< 25
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
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	< 3

Chemical name	Common name and synonyms	CAS number	%
GUAIPHENESIN	1,2-PROPANEDIOL, 3-(2-METHOXYPHENOXY)- * 3-(2-METHOXYPHENOXY)-1,2-PROPANEDIOL * GLYCEROL GUAIACOLATE * GLYCEROL ALPHA-GUAIACYL ETHER * ALPHA-GLYCERYL GUAIACOLATE ETHER * GLYCERYL GUAIACOL ETHER * O-METHOXYPHENYL GLYCERYL ETHER * ROBITUSSIN * 1,2-DIHYDROXY-3-(2-METHOXYPHENOXY)PROPANE	93-14-1	< = 1
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
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID * CITIRIC ACID	77-92-9	< 0.5
PHENYLEPHRINE HYDROCHLORIDE	(-)-M-HYDROXY-ALPHA-((METHYLAMINO)METHYL)BENZYL ALCOHOL HYDROCHLORIDE * ISOPHRIN HYDROCHLORIDE * LEVOPHENYLEPHRINE HYDROCHLORIDE * METAOXEDRINE HYDROCHLORIDE * META-SYNEPHRINE HYDROCHLORIDE * NEOPHRYN * NEO-SYNEPHRINE HYDROCHLORIDE * L-PHENYLEPHRINE HYDROCHLORIDE * BENZENEMETHANOL, 3-HYDROXY-ALPHA-(METHYLAMINO)METHYL)-, HYDROCHLORIDE, (R)-	61-76-7	< 0.1
Other components below reportable levels			< 61

*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. Get medical attention if symptoms occur. Take off contaminated clothing and wash before reuse.

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). Do not induce vomiting without advice from poison control center. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed None known.

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 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 breathe mist or vapor. 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. Do not breathe mist or vapor. 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 and sources of ignition. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3
	OHC	1
D-SORBITOL (CAS 50-70-4)	OHC	1
GUAIPHENESIN (CAS 93-14-1)	8 HR TWA	600 mcg/m3
	OHC	2
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	15 MIN STEL	200 mcg/m3
	8 HR TWA	30 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

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

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.

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

Skin protection

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.

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. 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.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Syrupy 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 °F (38 °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	56.1 % 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.
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	May be 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. Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	None known.

Information on toxicological effects

Acute toxicity May be harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
Acute		
Oral		
LD50	Rat	15.9 g/kg
ETHANOL (CAS 64-17-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Chronic		
Oral		
LOAEL	Monkey	40 %, 48 months % ingested calories

Components	Species	Test Results
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
GUAIPHENESIN (CAS 93-14-1)		
Acute		
Oral		
LD50	Rat	1510 mg/kg
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
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)		
Acute		
Oral		
LD50	Rat	350 mg/kg
Subacute		
Oral		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.

Components	Species	Test Results
Subchronic		
Oral		
LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study
	Rat	5000 - 20000 ppm, 12 weeks dietary study
LOAEL	Mouse	1250 ppm, 12 weeks dietary study
	Rat	1250 ppm, 12 weeks dietary study
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

PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Non-irritant Species: Rabbit Notes: US Pharmacopeia

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

PARACETAMOL	OECD 404, Literature data Result: Slight 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

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Result: Pharmacological, cardiovascular effects. Species: Human
ETHANOL	OECD 405 Result: Severe Species: Rabbit
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Irritant

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Opthalmology Result: Low incidence of contact hypersensitivity. Species: Human
ETHANOL	OECD 406 Result: Negative Species: Guinea pig
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

ETHANOL	Ames Result: Negative

Mutagenicity

PHENYLEPHRINE HYDROCHLORIDE	Ames Result: Negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Ames, Literature data Result: Negative
ETHANOL	Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative
PHENYLEPHRINE HYDROCHLORIDE	Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Chromosomal Aberration Assay In Vitro, Literature data Result: Positive
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
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
PHENYLEPHRINE HYDROCHLORIDE	L5178Y mouse lymphoma thymidine kinase locus assay Result: Equivocal Notes: NTP Study report - Phenylephrine.
ETHANOL	L5178Y mouse lymphoma thymidine kinase locus assay Result: Weakly positive
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: Negative
ETHANOL	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
PHENYLEPHRINE HYDROCHLORIDE	sister chromatid exchange Result: Positive Notes: NTP Study report - Phenylephrine.

Carcinogenicity Health injuries are not known or expected under normal use. Contains a material (ethanol) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

Carcinogenicity

PHENYLEPHRINE HYDROCHLORIDE	133 - 270 mg/kg/day Result: Negative Species: Mouse Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride. 24 - 50 mg/kg/day Result: Negative Species: Rat Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.
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
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: Negative
ETHANOL	inadequate study Result: Increase in liver sarcomas Species: Mouse 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 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

Reproductivity

ETHANOL	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
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
GUAIPHENESIN	Embryofetal Development, Epidemiology Result: No clear association with developmental effects. Species: Human
ETHANOL	Embryofetal Development, in utero - 36% total calories Species: Rat Organ: gonadal growth and development
PHENYLEPHRINE HYDROCHLORIDE	Epidemiology Result: Equivocal, evidence of malformations, or other adverse foetal effectw from clinical use. Other studies show no such association. Species: Human
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
PHENYLEPHRINE HYDROCHLORIDE	Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure. Species: Rabbit

Specific target organ toxicity - single exposure May cause damage to organs.

Specific target organ toxicity - single exposure

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Organ: Cardiovascular effects, some marked.
PARACETAMOL	Species: Human Organ: Liver

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

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

Chronic effects Prolonged exposure may cause chronic effects.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test
Microtox	EC50	Microtox	14 mg/l, 15 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
GUAIPHENESIN (CAS 93-14-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 24 hours
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
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.86 mg/l, 48 hours Measured
	NOEC	Daphnia	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured

Components		Species	Test Results
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours

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

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)

CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge
ETHANOL	37 - 86 %, 5 days BOD5, Activated sludge
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge
PHENYLEPHRINE HYDROCHLORIDE	81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

D-SORBITOL	-2.2
ETHANOL	-0.31
GUAIPHENESIN	-0.98
PARACETAMOL	0.36
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).

Bioconcentration factor (BCF)

D-SORBITOL	1 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

D-SORBITOL	0.3 Estimated
ETHANOL	1.2 Calculated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C
D-SORBITOL	0 atm m^3/mol Estimated
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

UN number UN1170

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

IATA

Not regulated as dangerous goods.

Not subject to provisions of IATA, see SP A58.

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.

Not subject to provisions of IMDG, see SP 144.

DOT

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	08-01-2014
Revision date	08-01-2014
Version #	12
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 3* Flammability: 3 Physical hazard: 0
NFPA ratings	Health: 3 Flammability: 3 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information	Product and Company Identification: Business Units Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Toxicological Information: Transport Information: Proper Shipping Name/Packing Group Regulatory Information: United States GHS: Classification