SAFETY DATA SHEET

1. Identification

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

Other means of identification

Synonyms MFC 50/56 * PARACETAMOL, GUAIPHENESIN AND PHENYLEPHRINE HYDROCHLORIDE, 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
D-SORBITOL Sorbitol L-GULITOL 1,2,3,4,5,6-HEXANEHEXOL D-SORBOL	50-70-4	< 20

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
GLYCERIN Glycerol GLYCERIN ANHYDROUS Glycerine GLYCERITOL GLYCYL ALCOHOL 1,2,3-Propanetriol PROPANETRIOL GLYROL GLYSANIN TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE OSMOGLYN	56-81-5	< = 20
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	< = 10
PARACETAMOL ACETAMIDE, N-(4-HYDROXYPHENYL)- ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PANADOL PARACETAMOL TYLENOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE	103-90-2	< 3
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

ACESULFAME K 1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) ACESULFAM	55589-62-3	< 0.5
CITRIC ACID ANHYDROUS BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID CITIRIC ACID	77-92-9	< 0.5
SODIUM CITRATE, ANHYDROUS CITREME	68-04-2	< 0.5
XANTHAN GUM ACTIGUM CX 9 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 GALAXY XB KELFLO KELTROL (GUM) KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 XANFLOOD XANTHOMONAS GUM	11138-66-2	< 0.2
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		< 35

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 medical advice. Get medical attention if symptoms occur.
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	Not established.
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	Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water.
Specific hazards arising from the chemical	Vapours may form explosive mixtures with air. Vapours 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 fire fighters	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.
Hazchem Code	Not available.
General fire hazards	Flammable liquid and vapour.
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 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 vapour. 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.
For emergency responders	Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
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 vapours or divert vapour 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.

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 vapour. Avoid prolonged exposure. 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 and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK

Components	Type	Value
ACESULFAME K (CAS 55589-62-3)	OHC	1

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
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)	8 HR TWA	5000 mcg/m3
	OHC	1
XANTHAN GUM (CAS 11138-66-2)	OHC	1

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	
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Inhalable mist.

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	
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Inspirable dust.
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.
		150 ppm	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	
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m3	Inhalable dust.
Propylene glycol (CAS 57-55-6)	TWA	474 mg/m3	Total vapour and particulates.
		10 mg/m3	Particulate.
		150 ppm	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	Form
ETHANOL (CAS 64-17-5)	TWA	960 mg/m3 500 ppm	
GLYCERIN (CAS 56-81-5)	TWA	50 mg/m3	Inhalable fraction.

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

Appropriate engineering controls 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. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

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

Respiratory protection No personal respiratory protective equipment normally required. 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 Syrupy liquid.

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 37 - 40 °C (98.6 - 104 °F) 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.

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.

Other physical and chemical parameters

Percent volatile	78.2 % 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	Keep away from heat, sparks and open flame. Avoid temperatures exceeding the flash point. 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 products decomposition.

11. Toxicological information

Information on possible routes of exposure

Ingestion	May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Prolonged inhalation may be harmful. May cause damage to organs by 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 exposure	Not established.
Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
ACESULFAME K (CAS 55589-62-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
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
Subacute		
Oral		
LOEL	Rat	16.9 g/kg, 4 weeks Dietary - Dose given as g/kg/day
		6 %, 4 weeks percent in diet - continuous

Components	Species	Test results
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
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
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
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 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/irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

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 sensitisation

Skin sensitisation None known. This product is not expected to cause skin sensitisation.

Sensitisation

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
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: Time to tumour reduced Species: Mouse Test Duration: 80 weeks 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

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.

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.

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

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
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
Acute			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 10000 mg/l
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

Components		Species	Test results
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
Propylene glycol (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM CITRATE, ANHYDROUS (CAS 68-04-2)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	161 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	2031 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	590 - 1018 mg/l, 96 hours Static test
Microtox	EC50	Microtox	18.8 mg/l, 15 minutes
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

* 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
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)

ACESULFAME K	0 - 8 %, 25 days Batch activated sludge (BAS), Activated sludge
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

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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
Propylene glycol	62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge
SODIUM CITRATE, ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Anaerobic biodegradation)

Propylene glycol	100 %, 9 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

D-SORBITOL	-2.2
ETHANOL	-0.31
GLYCERIN	-1.76
GUAIPHENESIN	-0.98
PARACETAMOL	0.36
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).
Propylene glycol	-0.92 -1.35

Bioconcentration factor (BCF)

D-SORBITOL	1 Estimated
Propylene glycol	< 1 Estimated

Mobility in soil Not available.

Adsorption

Soil/sediment sorption - log Koc

D-SORBITOL	0.3 Estimated
ETHANOL	1.2 Calculated

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
Propylene glycol	0 atm m^3/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).

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.

Not subject to provisions of IATA, see SP A58.

IMDG

Not regulated as dangerous goods.

Not subject to provisions of IMDG, see SP 144.

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

General information Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

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

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

PARACETAMOL (CAS 103-90-2)	applies to all preparations in any concentration Use Warning Statement 97 and/or Warning Statement 98., Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised to by a doctor., Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor., If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 131 - 126; New Zealand 0800 - 764 - 766) or go to a hospital straight away even if you feel well

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

GUAIPHENESIN (CAS 93-14-1)	applies to all preparations in any concentration Exception may apply, see the regulation for relevance.
PARACETAMOL (CAS 103-90-2)	for therapeutic use Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 3

PARACETAMOL (CAS 103-90-2)	> 10

Australia Medicines & Poisons Schedule 4

GUAIPHENESIN (CAS 93-14-1)	in preparations for human therapeutic use Exception may apply, see the regulation for relevance.
PARACETAMOL (CAS 103-90-2)	applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

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)

CITRIC ACID ANHYDROUS (CAS 77-92-9)	1000 - 9999 TONNES See the regulation for additional information.
D-SORBITOL (CAS 50-70-4)	1000 - 9999 TONNES See the regulation for additional information.
ETHANOL (CAS 64-17-5)	10000 - 99999 TONNES See the regulation for additional information.
GLYCERIN (CAS 56-81-5)	1000 - 9999 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 Deleting 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.

Resricted 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)	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

Country(s) or region	Inventory name	On inventory (yes/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	06-August-2014
Revision date	06-August-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: Regulatory Information: United States GHS: Classification