

# SAFETY DATA SHEET

1. Identification	
Product identifier	DAY NURSE LIQUID
Other means of identification	
Synonyms	DAY NURSE LIQUID (UK) * R&D CODE B19/69 * PARACETAMOL, PSEUDOEPHEDRINE HYDRCHLORIDE AND PHOLCODINE, FORMULATED PRODUCT
Recommended use of the chemic	cal 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 impor	ter
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	of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
ANH ANH ETH Ethy ETH ETH	- OHOL ANHYDROUS IYDROUS ETHANOL IYDROUS ETHYL ALCOHOL IANOL 200 PROOF I alcohol IYL ALCOHOL USP 200 PROOF (USI) IYL ALCOHOL, 100%	64-17-5	5
GR/	IYL HYDROXIDE AIN ALCOHOL IANOL		

PRACETAND:         103-90-2         3.3           ACETAMUER_AL-HYDROXYPHENYL):         103-90-2         3.3           ACETAMUER_AL-HYDROXY-ACETAMULDE         PARADOL         PARADOL           PARADOL         PARADOL         945-78-8         0.2           (S(R''R')ALPHA'L'MENTYLANINOJETHYLJBENZENEMETHANOL         HYDROCHLORIDE         0.2           (H'PARADOL         PARADOL         91.47         0.3           PHOLCODINE         509-67-1         0.03         0.47           CODECODINE         10.488         91.47         0         0           A. FIRST-BIDENNE HYDROCHLORIDE         10.488         10         0.489         0         0.47         0.43           Skin contact         In cas				
ACETANILDE, 4/HYDROXY- 4/HYDROXYACETANILDE PARAADOL PARACETAMILOPHENOL 4/PSLEDOEPHEDRINE HYDROCHLORIDE D-PSEUDOEPHEDRINE HYDROCHLORIDE 7/U/S1 PHOLCODINE GR 45006 1033 (GW ACN) RTECS US96000 (+)-PSLEPHEDRINE HYDROCHLORIDE 1/U/S1 PHOLCODINE GR 4520X Other components below reportable levels 91,47 4. First-aid measures Inhalation Incase 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 attrificial respiration. Get medical attention immediately. Skin contact Ingestion Inges	PARACETAMOL		103-90-2	3.3
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(+)PS-LEPHEDRINE       FUDROCHLORIDE         71U51       509-67-1       0.03         GR140220X       91.47         Other components below reportable levels       91.47         4. First-aid measures       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 clothin and shoes. Take off immediately all contaminated clothin.         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 centre immediately. Do not induce vomiting without medical advice.         Personal protection for first-aid       Take off all contaminated clothing immediately. In the case of accident or if you feel unwell, seek madro 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.         Symptoms caused by exposure       No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.         5. Fire-fighting measures       Suitable exinguishing m				
PHOLCODINE GR140220X       509-67-1       0.03         Other components below reportable levels       91.47         4. First-aid measures       91.47         Description of necessary 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, and the personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention 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 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 centre immediately. Do not induce vomiting without medical advice immediately (involved, and take precautions to protect thor of you feel unwell, seek medical advice immediately (involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.         Symptoms caused by exposure       Direct contact with eyes may cause temporary irritation.         Medical attention and special reatment       Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).         Stribe chinguishing media       Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).         Specific hazards arising from the chemical equipment/instructions       Vapours may form explosive mixtures with air. Vapours may travel considerable distance to a source of ignition and flash back. Durin		DROCHLORIDE		
GR140220X       Other components below reportable levels       91.47         4. First-aid measures       Description of necessary 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, fush 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 centre immediately. Do not induce vomiting without medical advice/attention.         Personal protection for first-aid responder are of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.         Symptoms caused by exposure       Direct contact with eyes may cause temporary irritation.         No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.         5. Fire-fighting measures       Suitable extinguishing media         Suitable extinguishing media       Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).         Specific hazards arising from the chemical breathing apparatus an	71U51			
Other components below reportable levels     91.47       4. First-aid measures     Description of necessary first aid measures     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 clothin 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 centre immediately. Don ti nduce vomiting without medical advice.       Personal protection for first-aid     Take off all contaminated clothing immediately. In the case of accident or if you feel unwell, seek medical advice.       Symptoms caused by exposure     Direct contact with eyes may cause temporary irritation.       No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.       5. Fire-fighting measures     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.       Specific protective equipment and precautions for fire and/or explosion do not breath fures.     Self-contained breathin	PHOLCODINE		509-67-1	0.03
4. First-aid measures         Description of necessary 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. 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 centre immediately. Do not induce vomiting without medical advice.         Personal protection for first-aid       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.         Symptoms caused by exposure       Direct contact with eyes may cause temporary irritation.         Medical attention and special treatment       Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).         Medical attention and special medical break ing apparatus and full protective clothing must be worn in case of fire.       Self-contained break ing apparatus and full protectic clothing must be worn in case of fire.	GR140220X			
Description of necessary first aid measures         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 clothin 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, cal a poison control centre immedicately. Do not induce vomiting without medical advice.           Personal protection for first-aid         Take off all contaminated clothing immediately. In the case of accident or if you feel unwell, seek responders           Symptoms caused by exposure         Direct contact with eyes may cause temporary irritation.           No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.           5. Fire-fighting measures         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.           Specific hazards arising from the chemical paparatus and full protective clothing must be worn in case of fire. and/or explosion do not breathe fumes.	Other components below repor	table levels		91.47
Description of necessary first aid measures         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 clothin 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, cal a poison control centre immedicately. Do not induce vomiting without medical advice.           Personal protection for first-aid         Take off all contaminated clothing immediately. In the case of accident or if you feel unwell, seek responders           Symptoms caused by exposure         Direct contact with eyes may cause temporary irritation.           No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.           5. Fire-fighting measures         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.           Specific hazards arising from the chemical paparatus and full protective clothing must be worn in case of fire. and/or explosion do not breathe fumes.	4. First aid massion			
InhalationIn case of accident by inhalation: remove casuality 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 contactImmediately flush with plenty of water for at least 15 minutes while removing contaminated clothin and shoes. Take off immediately all contaminated clothing. Get medical attention if symptoms occur.Eye contactRinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If eye iritation persists: Get medical advice/attention.IngestionIf 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.Personal protection for first-aid respondersTake 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.Symptoms caused by exposure treatmentDirect contact with eyes may cause temporary irritation. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.S. Fire-fighting media Suitable extinguishing mediaAlcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2). Water.Specific hazards arising from the chemical precutions for fire- fighting equipment/instructionsSelf-contained breathing apparatus and full protective clothing must be worn in case of fire. a				
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Hazchem Code Not available.		in case of the analor explosion do not breathe fume		
		Not available.		
	General fire hazards	Combustible liquid.		

#### 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 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. 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,	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store in a

**Conditions for safe storage, including any incompatibilities includin** 

### 8. Exposure controls and personal protection

Follow standard monitoring procedures.

### **Occupational exposure limits**

**Control parameters** 

GSK	<b>T</b>	Mahar
Components	Туре	Value
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PSEUDOEPHEDRINE HYDROCHLORIDE (CAS 345-78-8)	8 HR TWA	200 mcg/m3
	OHC	2
Australia, National Workplace OE	Ls (Workplace Exposure Standa	ards for Airborne Contaminants, Appendix A)
Components	Туре	Value
ETHANOL (CAS 64-17-5)	TWA	1880 mg/m3
		1000 ppm
Australia. OELs. (Adopted Nation Environment)	al Exposure Standards for Atmo	ospheric Contaminants in the Occupational
Components	Туре	Value
ETHANOL (CAS 64-17-5)	TWA	1880 mg/m3
		1000 ppm

Components	Туре	Value	
ETHANOL (CAS 64-17-5)	STEL	1000 ppm	
UK. EH40 Workplace Expos	sure Limits (WELs)		
Components	Туре	Value	Form
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3	
PARACETAMOL (CAS 103-90-2)	TWA	1000 ppm 10 mg/m3	Inhalable dust.
Germany. DFG MAK List (a in the Work Area (DFG)	dvisory OELs). Commission for the	Investigation of Health Haza	rds of Chemical Compounds
Components	Туре	Value	
ETHANOL (CAS 64-17-5)	TWA	960 mg/m3 500 ppm	
ological limit values	No biological exposure limits noted	for the ingredient(s).	
ntrols	changes per hour) should be used. applicable, use process enclosures maintain airborne levels below reco established, maintain airborne level is established for operations involvin Category and the outcome of a site	local exhaust ventilation, or of mmended exposure limits. If ex s to an acceptable level. An Ex ng this material based upon the or operation-specific risk asse	ther engineering controls to xposure limits have not been xposure Control Approach (ECA > OEL/Occupational Hazard
Eye/face protection	, for example personal protective ec Not normally needed. If contact is li		hields are recommended.
Skin protection		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Hand protection	The choice of an appropriate glove features and is different from one pl any solvents and other hazards pre	oducer to the other. Glove sele	
Other	Not normally needed. Wear suitable contamination.	e protective clothing as protection	on against splashing or
Respiratory protection	No personal respiratory protective e maintain airborne concentrations be acceptable level (in countries where respirator must be worn.	low recommended exposure li	mits (where applicable) or to ar
Thermal hazards	Wear appropriate thermal protective	e clothing, when necessary.	
/giene measures	For advice on suitable monitoring m and safety professional. When usin An occupational/industrial hygiene i	g do not smoke. Wash hands a	ifter handling and before eating

# 9. Physical and chemical properties

	•
Appearance	
Physical state	Liquid.
Form	Solution.Bottle.
Colour	Orange.
Odour	Not available.
Odour threshold	Not available.
рН	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	70 °C (158 °F) Closed cup (Estimation based on components).
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

# Upper/lower flammability or explosive limits

Upper/lower flammability or exp	losive limits
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
10. Stability and reactivity	
Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents. Alkali metals

Incompatible materialsStrong oxidising agents. Alkali metals.Hazardous decomposition<br/>productsIrritating and/or toxic fumes and gases may be emitted upon the products decomposition.

# 11. Toxicological information

## Information on possible routes of exposure

information on possible routes	oi exposure		
Ingestion	Harmful if swallowed. However, exposure.	ingestion is not likely to be a primary route of occupational	
Inhalation	Under normal conditions of inte	nded use, this material is not expected to be an inhalation hazard.	
Skin contact	Health injuries are not known or	r expected under normal use.	
Eye contact	Health injuries are not known or	r expected under normal use.	
Symptoms related to exposure	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache, insomnia.		
Acute toxicity	Harmful if swallowed. Health injuries are not known or expected under normal use.		
Components	Species	Test results	
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 parameter
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 wate - continuous
PARACETAMOL (CAS 103-	90-2)	continuous
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	M	
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
PHOLCODINE (CAS 509-67	-1)	
Acute		
Oral		
LD50	Mouse	1000 RTECS Database
PSEUDOEPHEDRINE HYDR	ROCHLORIDE (CAS 345-78-8)	
Acute		
Oral		
LD50	Mouse	371 mg/kg
* Estimates for product r	may be based on additional com	ponent data not shown.
Skin corrosion/irritation	Health injuries are not kr	own or expected under normal use.
Corrosivity		
ETHANOL		OECD 404 Result: Negative; not considered a significant irritant Species: Rabbit
Irritation Corrosion - S		
PSEUDOEPHEDRI PARACETAMOL	NE HYDROCHLORIDE	0.2 OECD 404, Literature data Result: Slight irritant Species: Rabbit

Eye		
ETHANOL		OECD 405
		Result: Severe
		Species: Rabbit
PARACETAMOL		OECD 405 Result: Slight irritant
		Species: Rabbit
Eye / Initial pain reaction sc	ore	
PARACETAMOL		Literature data
Respiratory or skin sensitisation		
Respiratory sensitisation	-	or expected under normal use.
Skin sensitisation	Health injuries are not known	or expected under normal use.
Sensitisation		
ETHANOL		OECD 406 Result: negative
		Species: Guinea pig
Germ cell mutagenicity	Health injuries are not known	or expected under normal use.
Mutagenicity		
ETHANOL		Ames
PARACETAMOL		Result: negative Ames, Literature data
		Result: negative
ETHANOL		Chromosomal Aberration Assay In Vitro, CHO cells
PARACETAMOL		Result: negative Chromosomal Aberration Assay In Vitro, Literature data
TARACETAMOL		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 In vivo Micronucleus, Literature data
PARACETAMOL		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

Mutagenicity		
ETHANOL	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	
PARACETAMOL	Organ: oral cavity, larynx, pharynx, oesophagus, liver Literature data	
	Result: Equivocal. Increase in ademomas at toxic dose. Species: Mouse	
	Literature data Result: Equivocal. Liver and bladder neoplasms at toxic do	202
	Species: Rat	303.
	Literature data	
	Result: negative Species: Mouse	
	Literature data	
	Result: negative	
ETHANOL	Species: Rat Neonatal, inadequate study	
ETHANOL	Result: negative	
	Species: Rat	
	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	
	Evaluation of Carcinogenicity	
PARACETAMOL (CAS 10		rdoro in
Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive diso laboratory animals. Health injuries are not known or expected under normal use. These eff linked only to high doses of this substance; low doses did not produce this adverse effect.	
Specific target organ toxicity -	May cause damage to organs by ingestion.	
single exposure		
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.	
Chronic effects	Prolonged inhalation may be harmful. Prolonged exposure may cause chronic effects.	
Other information	Caution - Pharmaceutical agent.	
12. Ecological information	ı	
Ecotoxicity	Not expected to be harmful to aquatic organisms.	

Components		Species		Test results
ETHANOL (CAS 64-17-5)				
Aquatic				
Acute			<i></i>	
Algae	EC50	Blue-green alg aeruginosa)	gae (Microcystis	1450 mg/l, 72 hours
Crustacea	EC50	Water flea (Da	aphnia magna)	9190 mg/l, 48 hours Static test
Fish	EC50	Fathead minne promelas)	ow (Adult Pimephales	14200 mg/l, 96 hours Flow-through test
		Rainbow trout	(Adult Salmo gairdneri)	13000 mg/l, 96 hours Static test
PARACETAMOL (CAS 103-9	90-2)			
Aquatic				
Acute	5050			
Algae	EC50	subspicatus)	Scenedesmus	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Da	aphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minne promelas)	ow (Juvenile Pimephales	814 mg/l, 96 hours Flow-through test
PSEUDOEPHEDRINE HYDR	ROCHLORIDE (C)	AS 345-78-8)		
Acute	10-50			
	IC50	Activated slud	-	> 100 mg/l, 3 hours
	NOEC	Activated slud	ge	3.2 mg/l, 3 hours
Aquatic				
Acute	E C E O	Croop algae (	Colonactrum	90 mg/L 70 hours
Algae	EC50	Green algae ( capricornutum	))	82 mg/l, 72 hours
Crustacea	EC50		aphnia magna)	> 120 mg/l, 48 hours Static test
	NOEC	Water flea (Da	aphnia magna)	7.5 mg/l, 48 hours Static test
Fish	EC50	Golden ide/orf idus)	e (Juvenile Leuciscus	460 - 1000 mg/l, 96 hours
Chronic				
Algae	NOEC	Green algae ( capricornutum		> 7.5 mg/l, 72 hours
Persistence and degradabi	lity			
Photolysis				
Half-life (Photolysi	s-aqueous)			
	ETHANOL <b>Half-life (Photolysis-atmospheric)</b> ETHANOL		1 - 36.6 years Measured	
			4 - 5.9 Days Estimated	
Hydrolysis				
Half-life (Hydrolysi PSEUDOEPHEDRI		RIDE	> 99 %, 14 days, Activa	ted sludge
Biodegradability			-	
Percent degradation	on (Aerobic biode	egradation-inhere		
ETHANOL			37 - 86 %, 5 days BOD5, Activated sludge 99 %, 5 days Modified Zahn-Wellens, Activated sludge	
PARACETAMOL Percent degradation (Aerobic biodegradation-ready)				Lann-Wellens, Activated sludge
PSEUDOEPHEDRINE HYDROCHLORIDE			60 % BOD20	
Bioaccumulative potential				
Partition coefficient n-octanol / water (log K	(ow)			
ETHANOL			-0.31	
PARACETAMOL PSEUDOEPHEDRINE HYDROCHLORIDE			0.36 0.89	
		_	0.00	

### Mobility in soil

•		
Adsorption Sludge/biomass distribution coefficient - log Kd PSEUDOEPHEDRINE HYDROCHLORIDE Soil/sediment sorption - log Koc ETHANOL		< -1.39 Measured 1.2 Calculated
Volatility Henry's law ETHANOL PARACETAMOL		0.000005 atm m3/mol Measured 0 atm m^3/mol Estimated
Other adverse effects	Not available.	
13. Disposal consideration	าร	
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

### ADG

Not regulated as dangerous goods.

### RID

Not regulated as dangerous goods.

# IATA

Not regulated as dangerous goods.

## IMDG

Not regulated as dangerous goods.

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

### 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)

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. Low toxicity. General: Any use Use pattern restricts hazard. Human therapeutic use

### Australia Medicines & Poisons Appendix F

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 PHOLCODINE (CAS 509-67-1)

Australia Medicines & Poisons Schedule 2 PARACETAMOL (CAS 103-90-2)

Australia Medicines & Poisons Schedule 3 PARACETAMOL (CAS 103-90-2)

Australia Medicines & Poisons Schedule 4

Australia Medicines & Poisons Schedule 5 Poisons schedule number not allocated.

PARACETAMOL (CAS 103-90-2)

PHOLCODINE (CAS 509-67-1)

PHOLCODINE (CAS 509-67-1)

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

pholcodine

for therapeutic use Exception may apply, see the regulation for relevance.

applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

> 10

applies to all preparations in any concentration Exception may apply, see the regulation for relevance. applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

Listed. Exception may apply, see the regulation for relevance.

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 PHOLCODINE (CAS 509-67-1) Australia Medicines & Poisons Schedule 9 Poisons schedule number not allocated. Australia National Pollutant Inventory (NPI): Threshold quantity ETHANOL (CAS 64-17-5) 10 TONNES/YR Threshold Category: 1 **High Volume Industrial Chemicals (HVIC)** ETHANOL (CAS 64-17-5) 10000 - 99999 TONNES See the regulation for additional information. 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
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	08-September-2014
Revision date	08-September-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: Ingredients Physical & Chemical Properties: Ecological Information: Mobility TRANSPORT INFORMATION: Regulatory Information: Risk Phrases - Class. GHS: Classification