SAFETY DATA SHEET

1. Identification

Product identifier **BEECHAMS ULTRA ALL IN ONE CAPSULES**

Other means of identification

Synonyms PROJECT POD 2 * MFC 885081 * 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
PARACETAMOL	103-90-2	65.0 - 66.0
ACETAMIDE, N-(4-HYDROXYPHENYL)-		
ACETANILIDE, 4'-HYDROXY-		
4'-HYDROXYACETANILIDE		
PANADOL		
PARACETAMOL		
TYLENOL		
PARA-ACETAMIDOPHENOL		
4-ACETAMINOPHENOL		
PARA-HYDROXYACETANILIDE		

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	13.0 - 14.0
DODECYL SODIUM SULFATE DODECYL SULFATE, SODIUM SALT SODIUM LAURYL SULPHATE LAURYL SULFATE SODIUM SALT	151-21-3	<1.0
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	<1.0
Talc TALCUM, NON-ASBESTOS FORM Talc HYDROUS MAGNESIUM SILICATE	14807-96-6	<1.0
D&C YELLOW #10 C.I. ACID YELLOW 3 ACID YELLOW 3 D & C YELLOW NO.10 QUINOLINE YELLOW QUINOLINE YELLOW EXTRA	8004-92-0	<0.1
Titanium dioxide TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	<0.1
Other components below reportable levels		15.0 - 20.0

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.
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	None known.

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 Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Hazchem Code Not available.

General fire hazards No unusual fire or explosion hazards noted.

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. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimise dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. 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
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2
GUAIPHENESIN (CAS 93-14-1)	8 HR TWA	600 mcg/m3
	OHC	2
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3

GSK

Components	Type	Value
	OHC	1
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	15 MIN STEL	200 mcg/m3
	8 HR TWA	30 mcg/m3
	OHC	3

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inhalable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	2.5 mg/m3	
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inspirable dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Talc (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m3	Inhalable dust.
Talc (CAS 14807-96-6)	TWA	1 mg/m3	Respirable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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, 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 Solid.

Form Capsule.

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	Not available.
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.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials	Alkali metals.
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	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 exposure	None known.
Acute toxicity	Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
D&C YELLOW #10 (CAS 8004-92-0)		
Acute		
Oral		
LD50	Rat	2000 mg/kg
DODECYL SODIUM SULFATE (CAS 151-21-3)		
Acute		
Oral		
LD50	Rat	1288 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.
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

Components	Species	Test results
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* 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.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human
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.

Eye

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Result: Pharmacological, cardiovascular effects. Species: Human
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit

Eye

TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE	Supplier SDS Result: Irritant

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Respiratory or skin sensitisation

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

Sensitisation

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure
PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Opthalmology Result: Low incidence of contact hypersensitivity. Species: Human
TITANIUM DIOXIDE	Patch test, Literature data Result: negative Species: Human
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

PHENYLEPHRINE HYDROCHLORIDE	Ames Result: negative Notes: NTP Study report - Phenylephrine.
PARACETAMOL	Ames, Literature data Result: negative
TITANIUM DIOXIDE	Ames, Literature data 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 HPRT gene mutation in human lymphocytes, Literature data Result: negative 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.
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: positive
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: negative WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data 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 (titanium dioxide) classified as a carcinogen by external agencies. Titanium Dioxide produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

Carcinogenicity

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
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.
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months
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
GUAIPHENESIN	SAR / QSAR, DEREK, Lhasa, UK Result: negative

ACGIH Carcinogens

TALC (CAS 14807-96-6)	A4 Not classifiable as a human carcinogen.
TITANIUM DIOXIDE (CAS 13463-67-7)	A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
TALC (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 3 Not classifiable as to carcinogenicity to humans.
TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic 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 Causes 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.
Other information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
DODECYL SODIUM SULFATE (CAS 151-21-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	5.4 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.6 mg/l, 96 hours Flow-through test
Chronic			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	30 mg/l, 72 hours
Crustacea	NOEC	Ceriodaphnia dubia	0.88 mg/l, 7 days Flow-though Test
Fish	NOEC	Fathead minnow (Pimephales promelas)	3.8 mg/l, 28 days Flow-through 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
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
Talc (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours Static test

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

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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

Percent degradation (Aerobic biodegradation-ready)

DODECYL SODIUM SULFATE	95 % OECD 301 B

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DODECYL SODIUM SULFATE	1.6
GUAIPHENESIN	-0.98
PARACETAMOL	0.36
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).

Mobility in soil Not available.

Mobility in general Not available.

Volatility

Henry's law

PARACETAMOL	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.

IMDG

Not regulated as dangerous goods.

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

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

Poisons schedule number not allocated.

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

DODECYL SODIUM SULFATE (CAS 151-21-3)	for external use for the treatment of cats and dogs in preparations If in eyes wash out immediately with water.

	in other [unspecified] preparations If in eyes wash out immediately with water., If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

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

DODECYL SODIUM SULFATE (CAS 151-21-3)	applies to all preparations in any concentration Exception may apply, see the regulation for relevance.

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.

High Volume Industrial Chemicals (HVIC)

TALC (CAS 14807-96-6)	100000 - 999999 TONNES See the regulation for additional information.
TITANIUM DIOXIDE (CAS 13463-67-7)	100000 - 999999 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	27-August-2014
Revision date	27-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: