SAFETY DATA SHEET

1. Identification

Product identifier **NIGHT NURSE CAPSULES**

Other means of identification

Synonyms PARACETAMOL, PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE, 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	< 90
ACETAMIDE, N-(4-HYDROXYPHENYL)- ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PANADOL PARACETAMOL TYLENOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE		

LACTOSE D-LACTOSE 4-O-BETA-D-GLACTOPYRANOSYL-D-GLUCOSE MILK SUGAR LACTIN 4-(BETA-D-GALACTOSIDO)-D-GLUCOSE	63-42-3	< 12
PROMETHAZINE HYDROCHLORIDE 10-(2-(DIMETHYLAMINO)PROPYL)-PHENOTHIAZINE, MONOHYDROCHLORIDE 10H-PHENOTHIAZINE-10-ETHANAMINE, N,N,ALPHA-TRIMETHYL-, MONOHYDROCHLORIDE 173U48 HYDROCHLORIDE 3277 R.P. HL 8700 N,N,ALPHA-TRIMETHYL-10H-PHENOTHIAZINE-10-ETHANAMINE, MONOHYDROCHLORIDE PHENOTHIAZINE, 10-(2-(DIMETHYLAMINO)PROPYL)-, MONOHYDROCHLORIDE PROMETHAZINE HCL RM 436 RTECS SO8225000 SKF-1498A	58-33-3	< 2
DEXTROMETHORPHAN HYDROBROMIDE 9ALPHA,13ALPHA,14ALPHA-MORPHINAN, 3-METHOXY-17-METHYL-, HYDROBROMIDE DEXTROMETHORPHAN BROMIDE METHORATE HYDROBROMIDE C18H25NO.HBr	125-69-9	< 1.5
Silicon dioxide Silica Silica gel Amorphous silica DIATOMACEOUS EARTH INFUSORIAL EARTH CAB-O-SIL M-5	7631-86-9	< 0.25
Other components below reportable levels		< 1

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 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. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses.
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	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	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.
Medical attention and special treatment	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

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. 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. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. 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 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
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)	8 HR TWA	10 mcg/m3
	OHC	4
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)	8 HR TWA	10 mcg/m3
	OHC	4
Silicon dioxide (CAS 7631-86-9)	OHC	1

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

Components	Type	Value	Form
Silicon dioxide (CAS 7631-86-9)	TWA	2 mg/m3	Respirable dust.

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

Components	Type	Value	Form
Silicon dioxide (CAS 7631-86-9)	TWA	2 mg/m3	Respirable fraction.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
PARACETAMOL (CAS 103-90-2)	TWA	10 mg/m3	Inhalable dust.
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.

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

Appropriate engineering controls Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

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

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

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

9. Physical and chemical properties

Appearance

Physical state 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.
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.
Symptoms related to exposure	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.
Acute toxicity	Harmful if swallowed. Health injuries are not known or expected under normal use.

Components	Species	Test results
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)		
Acute		
Oral		
LD50	Rat	350 mg/kg
LACTOSE (CAS 63-42-3)		
Acute		
Oral		
LD50	Rat	> 10 g/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg

Components	Species	Test results
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
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)		
Acute		
Oral		
LD50	Mouse	326 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.

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

PARACETAMOL
OECD 405
Result: Slight irritant
Species: Rabbit

Eye / Initial pain reaction score

PARACETAMOL
Literature data

Respiratory or skin sensitisation

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

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

Sensitisation

DEXTROMETHORPHAN HYDROBROMIDE
SAR, DEREK, Lhasa, UK
Result: positive

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

Mutagenicity

DEXTROMETHORPHAN HYDROBROMIDE
Ames
Result: negative
Notes: Global Safety Datasheet.

PARACETAMOL
Ames, Literature data
Result: negative
Chromosomal Aberration Assay In Vitro, Literature data
Result: positive
HPRT gene mutation in human lymphocytes, Literature data
Result: negative

DEXTROMETHORPHAN HYDROBROMIDE
In vitro cytogenetics assay
Result: negative
Notes: Aardema A et al, Reg Tox Pharm.

PARACETAMOL
In vivo Micronucleus, Literature data
Result: negative
Species: Mouse

Carcinogenicity Health injuries are not known or expected under normal use.

Carcinogenicity

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

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

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

DEXTROMETHORPHAN HYDROBROMIDE	Organ: Central nervous system.
PARACETAMOL	Species: Human Organ: Liver

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

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

Other information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test results
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)			
Aquatic			
Acute			
Algae	EC50	Algae	2.28 mg/l, 72 hours
	NOEC	Algae	0.35 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	13.78 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	< 5.51 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.66 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 100 mg/l, 3 hours
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
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	1.5 mg/l, 48 hours
Fish	EC50	Fish	2 mg/l, 96 hours

Components		Species	Test results
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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

Percent degradation (Aerobic biodegradation-ready)

DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days

Bioaccumulative potential

Partition coefficient
n-octanol / water (log Kow)

PARACETAMOL	0.36
PROMETHAZINE HYDROCHLORIDE	-0.72

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

LACTOSE	1 Calculated

Volatility

Henry's law

LACTOSE	< 0 atm m3/mol Calculated
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. 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

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
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)	applies to all preparations in any concentration This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol., This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery., Use either Warning Statement 39 or 40.

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

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

PARACETAMOL (CAS 103-90-2)	applies to all preparations in any concentration Exception may apply, see the regulation for relevance.
PROMETHAZINE HYDROCHLORIDE (CAS 58-33-3)	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.

High Volume Industrial Chemicals (HVIC)

SILICON DIOXIDE (CAS 7631-86-9)	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
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	29-August-2014
Revision date	29-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: TOXICOLOGICAL INFORMATION: Regulatory Information: Risk Phrases - Class. GHS: Classification