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 Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- * ACETANILIDE, 4'-HYDROXY- * 4'-HYDROXYACETANILIDE * PANADOL * PARACETAMOL * TYLENOL * PARA-ACETAMIDOPHENOL * 4-ACETAMINOPHENOL * PARA-HYDROXYACETANILIDE	103-90-2	< 90
LACTOSE	D-LACTOSE * 4-O-BETA-D-GLACTOPYRANOSYL-D-GLUCOSE * MILK SUGAR * LACTIN * 4-(BETA-D-GALACTOSIDO)-D-GLUCOSE	63-42-3	< 12

Chemical name	Common name and synonyms	CAS number	%
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

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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 center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed
Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.

Indication of immediate medical attention and special treatment needed
No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

General information
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.

5. Fire-fighting measures

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 firefighters
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.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. 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 of the SDS.

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 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.

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/personal protection

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

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3

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, such as personal protective equipment

Eye/face protection
If contact is likely, safety glasses with side shields are recommended.

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.

Skin protection	
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. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	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.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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	Alkaline 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 likely 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 the physical, chemical and toxicological characteristics	Possible effects of overexposure in the workplace include: constipation, nausea, vomiting, headache.

Information on toxicological effects

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
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/eye 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 sensitization

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

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

Sensitization

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.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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.

Reproductivity

PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat 387 mg/kg/day Embryofetal Development, Literature data Result: Negative Species: Mouse 750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weght, minor skeletal abnormalities. Species: Rat

Reproductivity

PARACETAMOL	<= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
DEXTROMETHORPHAN HYDROBROMIDE	<= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rabbit Notes: Global Safety Datasheet.
	<= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rat Notes: Global Safety Datasheet.
PARACETAMOL	Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human

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.

Further 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

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

Mobility in general

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 instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

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

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

SILICON DIOXIDE (CAS 7631-86-9)

US. New Jersey Worker and Community Right-to-Know Act

SILICON DIOXIDE (CAS 7631-86-9)

US. Pennsylvania Worker and Community Right-to-Know Law

SILICON DIOXIDE (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 08-29-2014

Revision date 08-29-2014

Version # 14

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 2*
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 1
Instability: 0

References GSK Hazard Determination

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information
Product and Company Identification: Business Units
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Toxicological Information:
Regulatory Information: Risk Phrases - Class.
GHS: Classification