SAFETY DATA SHEET

1. Identification

Product identifier **PANADOL NIGHT TABLETS**

Other means of identification

Synonyms PANADOL NIGHT CAPLETS * PANADOL NIGHT PAIN TABLETS * PANADOL NIGHT PAIN RELIEF TABLETS * PARACETAMOL 500 MG AND DIPHENHYDRAMINE HYDROCHLORIDE 25 MG TABLETS * PARACETAMOL AND DIPENHYDRAMINE HYDROCHLORIDE, 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	< 80
STARCH	ARROWROOT STARCH * CORN STARCH * POTATO STARCH * RICE STARCH	9005-25-8	< 15
DIPHENHYDRAMINE HYDROCHLORIDE	2-(DIPHENYLMETHOXY)-N,N-DIMETHYLE THYLAMINE HYDROCHLORIDE * BENADRYL HYDROCHLORIDE * BENZHYDRAMINE HYDROCHLORIDE * DIFENHYDRAMINE HYDROCHLORIDE * BENADRYL	147-24-0	< 5

Chemical name	Common name and synonyms	CAS number	%
TALC	TALCUM, NON-ASBESTOS FORM * TALC * HYDROUS MAGNESIUM SILICATE	14807-96-6	< 5
POLYVINYLPYRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * PLASDONE	9003-39-8	< 0.5
Other components below reportable levels			< 6

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

4. First-aid measures

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

Most important symptoms/effects, acute and delayed Not established.

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 current prescribing information or to the local poison control information center.

General information 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.

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 Use water spray to cool unopened containers.

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 breathe dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the 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 of the SDS.

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. Minimize 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 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

Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Do not breathe dust. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. 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 in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0)	8 HTWA	200 mcg/m3
	OHC	2
PARACETAMOL (CAS 103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

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

Components	Type	Value	Form
TALC (CAS 14807-96-6)	TWA	0.3 mg/m3	Total dust.
		0.1 mg/m3	Respirable.
		20 millions of particle	
		2.4 millions of particle	Respirable.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

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, such as personal protective equipment

Eye/face protection

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

Hand protection

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

Skin protection

Other

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

Respiratory protection

No personal respiratory protective equipment normally required. 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	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	Tablet.
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. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials	Acids. 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. Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics Not established.

Information on toxicological effects

Acute toxicity Harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0)		
Acute		
Oral		
LD50	Rat	500 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
POLYVINYLPYRROLIDONE (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg

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

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin

DIPHENHYDRAMINE HYDROCHLORIDE
Acute dermal irritation; OECD 404, Supplier SDS
Result: Non-irritant
Species: Rabbit
Notes: Pfizer SDS

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. Direct contact with eyes may cause temporary irritation.

Eye

DIPHENHYDRAMINE HYDROCHLORIDE
Acute ocular irritation; OECD 405, Supplier SDS
Result: Non-Irritating
Species: Rabbit
Notes: Pfizer SDS

Eye

PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit
DIPHENHYDRAMINE HYDROCHLORIDE	REET Result: Positive

Eye / Initial pain reaction score

PARACETAMOL	Literature data

Respiratory or skin sensitization

Respiratory sensitization Not established.

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

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

PARACETAMOL	Ames, Literature data Result: Negative
DIPHENHYDRAMINE HYDROCHLORIDE	Ames, Literature data Result: Negative Notes: NTP study Chromosomal Aberration Assay In Vitro, CHO cells, Literature data Result: Positive at concentration toxic to cells Notes: CCRIS
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
DIPHENHYDRAMINE HYDROCHLORIDE	L5178Y mouse lymphoma thymidine kinase locus assay, Literature data Result: Negative Notes: NTP study Sister Chromatid Exchange, Supplier SDS Result: Negative

Carcinogenicity Health injuries are not known or expected under normal use. Contains a material (talc) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.

DIPHENHYDRAMINE HYDROCHLORIDE	156 - 313 ppm, Dietary study Species: Mouse Test Duration: 2 years Notes: NTP study 313 - 635 ppm, Dietary study Species: Rat Test Duration: 2 years Notes: NTP study
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.
POLYVINYLPYRROLIDONE (CAS 9003-39-8)	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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

Reproductivity

DIPHENHYDRAMINE HYDROCHLORIDE	25 - 100 mg/kg/day Embryo-foetal development, Literature data Result: Maternal toxicity; adverse foetal effects Species: Rat Notes: NTP study
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
DIPHENHYDRAMINE HYDROCHLORIDE	80 - 200 Embryo-foetal development, Literature data Result: Maternal toxicity, Foetotoxicity, some malformations. Species: Mouse Notes: NTP study
PARACETAMOL	<= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human

Specific target organ toxicity - single exposure Causes damage to organs.

DIPHENHYDRAMINE HYDROCHLORIDE	Organ: Central Nervous System.
PARACETAMOL	Species: Human Organ: Liver

Specific target organ toxicity - repeated exposure Causes damage to organs.

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

Chronic effects Prolonged exposure may cause chronic effects.

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
DIPHENHYDRAMINE HYDROCHLORIDE (CAS 147-24-0)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	0.35 mg/l, 96 hours Measured
	NOEC	Algae	0.26 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	2.3 mg/l, 48 hours Measured
	NOEC	Daphnia	< 0.56 mg/l
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	2.8 mg/l, 96 hours Static renewal test
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	1.1 mg/l

Components		Species	Test Results
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
POLYVINYLPYRROLIDONE (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
TALC (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test

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

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

DIPHENHYDRAMINE HYDROCHLORIDE	< 1 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge
POLYVINYLPYRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

DIPHENHYDRAMINE HYDROCHLORIDE	3.27 (Measured).
PARACETAMOL	0.36

Mobility in soil

Mobility in general

Volatility

Henry's law

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. Do not discharge into drains, water courses or onto the ground. 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

STARCH (CAS 9005-25-8)
TALC (CAS 14807-96-6)

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

TALC (CAS 14807-96-6)

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

STARCH (CAS 9005-25-8)
TALC (CAS 14807-96-6)

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
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 07-23-2014

Revision date 07-23-2014

Version # 12

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