

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	NIGHT NURSE LIQUID
Synonyms	NIGHT NURSE LIQUID (UK) * COLDREX NITE * PARACETAMOL, PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE, FORMULATED PRODUCT
Company Name	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
PARACETAMOL	103-90-2	5
PROMETHAZINE HYDROCHLORIDE	58-33-3	0.1
DEXTROMETHORPHAN HYDROBROMIDE	125-69-9	0.08
ETHANOL	64-17-5	18
NON-HAZARDOUS INGREDIENTS	Unassigned	76.8

3. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as flammable.
* Health	Exposure might occur via ingestion; skin; eyes. Possible effects of overexposure in the workplace include: symptoms similar to alcohol intoxication. Health effects information is based on hazards of components.
* Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of acetaminophen/paracetamol. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	This product is flammable. Fire and explosions might result if vapours are allowed to accumulate in the vicinity of a source of ignition.
Extinguishing Media	Carbon dioxide, dry powder or foam extinguishers are recommended. Do not use water extinguishers. Water jets may intensify the fire or be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal. Move containers from the fire area if possible without increased personal risk.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.
Environmental Precautions	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal. Equipment used for clean-up should be earthed (grounded) and non-sparking.

Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product. Detergent solutions can be used for clean-up and decontamination operations.
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7. HANDLING AND STORAGE

HANDLING

General Requirements This material contains flammable components. Ensure that any area in which this material is handled has sufficient ventilation to avoid the build up of vapour and to control employee potential exposure to volatiles below National Occupational Exposure Limits.

Ignition Controls Avoid contact with ignition sources. This liquid might ignite in contact with some types of ignition source.

STORAGE

Keep in tightly sealed containers or packages in a well-ventilated area. Keep away from sources of ignition. Follow storage instructions described in the product insert to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT PARACETAMOL
GSK Occupational Hazard Category 1
GSK Occupational Exposure Limit 4000 MCG/M3 (8 HR TWA)

INGREDIENT PROMETHAZINE HYDROCHLORIDE
GSK Occupational Hazard Category 4
GSK Occupational Exposure Limit 10 mcg/m3 (8 HR TWA)

INGREDIENT DEXTROMETHORPHAN HYDROBROMIDE
GSK Occupational Hazard Category 4
GSK Occupational Exposure Limit 10 mcg/m3 (8 HR TWA)

Other Equipment or Procedures None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity Clear.

Colour Dark green.

Physical Form Viscous liquid.

Odour Minty.

Flash Point 25 to 26 °C (Closed Cup) [Supports sustained combustion].

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid Avoid direct sunlight, conditions that might generate heat and sources of ignition.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: liver; central nervous system; symptoms similar to alcohol intoxication.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.
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ECOTOXICITY

Aquatic

Daphnid

This mixture contains an active pharmaceutical ingredient that is toxic to daphnids.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Not regulated according to IATA, IMDG, US DOT or ADR/RID requirements.

International Air Transport (IATA Requirements)

Classification and Labelling Not subject to provisions of IATA, see SP A58.

International Maritime Transport (IMDG Requirements)

Classification and Labelling Not subject to provisions of IMDG, see SP 144.

US Domestic Transport (DOT Requirements)

Classification and Labelling Not regulated according to US DOT requirements

European Ground Transport (ADR/RID Requirements)

Classification and Labelling Not subject to provisions of IMDG, see SP 144.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification Exempt when packaged for sale to consumers in a retail establishment.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 14-Dec-2006

SDS Version Number 15

SDS Sections Updated**Sections**

HAZARDS IDENTIFICATION

Subsections

Conditions Aggravated by Exposure

Environment

Eye Contact

Health

Ingestion

Inhalation

Overview

Skin Contact

Summary

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.