# SAFETY DATA SHEET

GlaxoSmithKline

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

**Material** **NIGHT NURSE CAPSULES**

**Synonyms** 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 | 86.5 |
| PROMETHAZINE HYDROCHLORIDE | 58-33-3 | 1.7 |
| DEXTROMETHORPHAN HYDROBROMIDE | 125-69-9 | 1.3 |
| NON-HAZARDOUS INGREDIENTS | Unassigned | 10.5 |

## 3. HAZARDS IDENTIFICATION

**Fire and Explosion** Expected to be non-combustible.

*** Health** Exposure might occur via ingestion; skin; eyes.
Health effects information is based on hazards of components.

*** Environment** Harmful to aquatic organisms.

## 4. FIRST-AID MEASURES

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| **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**

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| **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

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| **Fire and Explosion Hazards** | Not expected for the product, although the packaging is combustible. |
| **Extinguishing Media** | Water or foam extinguishers are recommended.<br>Carbon dioxide or dry powder extinguishers may be ineffective. |
| **Special Firefighting Procedures** | For single units (packages): No special requirements needed.<br>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.<br>If possible, contain and collect firefighting water for later disposal. |
| **Hazardous Combustion Products** | Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire. |

## 6. ACCIDENTAL RELEASE MEASURES

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| **Personal Precautions** | Wear protective clothing and equipment consistent with the degree of hazard. |
| **Environmental Precautions** | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. |
| **Clean-up Methods** | Collect and place it in a suitable, properly labelled container for recovery or disposal. |
| **Decontamination Procedures** | No specific decontamination or detoxification procedures have been identified for this product. |

## 7. HANDLING AND STORAGE

**HANDLING**

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| **General Requirements** | Avoid breaking or crushing capsules. |
| **STORAGE** | No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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|---|---|
| **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) |

**PERSONAL PROTECTIVE EQUIPMENT**

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| **Eye Protection** | Wear approved safety glasses with side shields if eye contact is possible. |
| **Other Equipment or Procedures** | An eye wash station should be available. Wash hands and arms thoroughly after handling. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

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| **Physical Form** | Hard gelatin capsule. |

## 10. STABILITY AND REACTIVITY

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| **Stability** | This product is expected to be stable. |
| **Conditions to Avoid** | None for normal handling of this product. |

## 11. TOXICOLOGICAL INFORMATION

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| **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** | Minor irritation might occur following direct contact with eyes. |
| **Target Organ Effects** | Adverse effects might occur in the following organ(s) following overexposure: liver. |
| **Sensitisation** | Sensitisation (allergic skin reaction) is not expected. |
| **Genetic Toxicity** | Not expected to be genotoxic under occupational exposure conditions. |
| **Carcinogenicity** | Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. |
| **Reproductive Effects** | No adverse effects have been reported following extensive use or exposure in humans. |

## 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 material to the environment. Local regulations and procedures should be consulted prior to environmental release.

**ECOTOXICITY**

**Aquatic**

**Daphnid** This mixture contains a major component(s) 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** Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

## 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** 13-Dec-2006 **SDS Version Number** 13

### SDS Sections Updated

| Sections | Subsections |
|---|---|
| HAZARDS IDENTIFICATION | Conditions Aggravated by Exposure |
| | Environment |
| | Eye Contact |
| | Health |
| | Ingestion |
| | Inhalation |
| | Overview |
| | Skin Contact |

## SDS Sections Updated

| Sections | Subsections |
|---|---|
| HAZARDS IDENTIFICATION | Summary |
| REGULATORY INFORMATION | US Environmental (EPA) Requirements |

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.