

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	NYTOL ONE A NIGHT CAPLETS
Synonyms	NYTOL ONE A NIGHT CAPLETS (UK) * FORMULA NUMBER IB-0987 * DIPHENHYDRAMINE HYDROCHLORIDE, FORMULATED PRODUCT
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	UK General Information: +44-20-8047-5000
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	Medical Emergency +1-612-221-3999, Ext 221
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	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
DIPHENHYDRAMINE HYDROCHLORIDE	147-24-0	14.3
NON-HAZARDOUS INGREDIENTS	Unassigned	85.7

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	Exposure might occur via; skin; eyes; ingestion. Possible effects of overexposure in the workplace include: symptoms similar to alcohol intoxication. Health effects information is based on hazards of components.
* Environment	Dangerous for the environment. Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

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.
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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 diphenhydramine. 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	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may 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.
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	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**

General Requirements Avoid breaking or crushing tablets.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	DIPHENHYDRAMINE HYDROCHLORIDE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	200 mcg/m ³ (8 HTWA)

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Tablet.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

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.

Sensitisation Allergic skin reactions might occur following dermal exposure.

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 Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects Overexposure in the workplace might have the following effects: activity in the nervous system.

12. ECOLOGICAL INFORMATION

*** Summary** This material contains an active pharmaceutical ingredient that has been tested, and which may be very toxic to aquatic organisms if released directly to the environment. This material contains an active pharmaceutical ingredient that may persist in the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. 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

*** Algal** This material contains an active pharmaceutical ingredient that is very toxic to algae.

*** Daphnid** This material contains an active pharmaceutical ingredient that is toxic to daphnids.

*** Fish** This material contains an active pharmaceutical ingredient that is toxic to fish.

MOBILITY

*** Partitioning** This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

*** Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).

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 17-Mar-2006

SDS Version Number 5

SDS Sections Updated

Sections

ECOLOGICAL INFORMATION

Subsections

Activated Sludge Respiration

Adsorption

Algal

Algal Degradation

Bioaccumulation

Biodegradation

Daphnid

Distribution

Earthworm

Ecotoxicity

Fish

GSK Environmental Hazard Category

Hydrolysis

Microbial Growth Inhibition

SDS Sections Updated**Sections**

ECOLOGICAL INFORMATION

HAZARDS IDENTIFICATION

REGULATORY INFORMATION

Subsections

Microtox

Mobility

Other Adverse Effects

Other Species - Aquatic

Other Species - Terrestrial

Partitioning

Persistence/Degradation

Photolysis

Solubility

Summary

Volatility

Environment

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.