



## Product Safety Data Sheet

<b>Document Code:</b>	D8059156	<b>Version :</b>	1.0
<b>Description:</b>	MUCNX NGHT PES DIPH APAP TABS	<b>Status:</b>	Published
<b>Project Name:</b>	Cha Cha Night	<b>Project Number:</b>	
<b>Category:</b>	Cough	<b>Segment:</b>	Multi Symptom Cough
<b>Formula Type:</b>	FILL FORMULA		

PSDS

PSDS

INFORMATION ON THE ACTIVE INGREDIENTS FOR ALL RECKITT BENCKISER  
HEALTHCARE (UK) LTD PHARMACEUTICAL PRODUCTS CAN BE OBTAINED FROM  
THE NATIONAL AND REGIONAL POISONS INFORMATION CENTRES.

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IN CASE OF EMERGENCY, CONTACT A MEDICAL PRACTITIONER OR RECKITT BENCKISER  
HEALTHCARE NORTH AMERICA INC.  
EMERGENCY CONTACT TELEPHONE NUMBER: 1-888-963-3382  
AND ASK FOR THE MEDICAL INFORMATION UNIT.

### 1. PRODUCT AND COMPANY IDENTIFICATION

#### Product Name

**MUCINEX SINUS-MAX DAY NIGHT MAXIMUM STRENGTH (acetaminophen, guaifenesin, phenylephrine hydrochloride, and diphenhydramine hydrochloride) kit**

#### Product Type

Caplet

#### Use

Temporarily relieves nasal congestion, headache, minor aches and pains, sinus congestion and pressure, runny nose and sneezing (Mucinex SINUS-MAX Night only), temporarily promotes nasal and/or sinus drainage, helps loosen phlegm (mucus) and thin bronchial passageways of bothersome mucus and make coughs more productive (Mucinex SINUS-MAX Day only)

#### Appearance

Orange colour caplets - Mucinex SINUS-MAX Day (TDS 0390598)

Blue colour caplets - Mucinex SINUS-MAX Night (TDS 8054601)

Supplier

Reckitt Benckiser Healthcare, Thane Road, Nottingham, NG90 2DB, UNITED KINGDOM

**Manufactured for:**

Reckitt Benckiser North America Inc.  
399 Interpace Parkway (P.O. Box 225)  
Parsippany  
New Jersey  
USA 07054-0225

Technical Services

N/A

**2. COMPOSITION****MUCINEX SINUS-MAX DAY MAXIMUM STRENGTH**

<b>Ingredient</b>	<b>CAS Number</b>
acetaminophen	103-90-2
guaifenesin	93-14-1
phenylephrine hydrochloride	61-76-7
croscarmellose sodium	74811-65-7
crospovidone	9003-39-8
FD&C red no. 40	68583-95-9
FD&C yellow no. 6	2783-94-0
aluminium oxide	1344-28-1
magnesium stearate	557-04-0
microcrystalline cellulose	9004-34-6
polyethylene glycol	25322-68-3
polyvinyl alcohol	9002-89-5
povidone K-30	9003-39-8
talc	14807-96-6
titanium dioxide	13463-67-7

**MUCINEX SINUS-MAX NIGHT MAXIMUM STRENGTH**

<b>Ingredient</b>	<b>CAS Number</b>
acetaminophen	103-90-2
diphenhydramine hydrochloride	147-24-0
phenylephrine hydrochloride	61-76-7
corn starch	9005-84-9
croscarmellose sodium	74811-65-7
crospovidone	9003-39-8
FD&C blue no. 1	68921-42-6
aluminium oxide	1344-28-1
hypromellose	9004-65-3
magnesium stearate	557-04-0
microcrystalline cellulose	9004-34-6
polydextrose	68424-04-4
polyethylene glycol	25322-68-3
povidones	9003-39-8
silicon dioxide	7631-86-9
stearic acid	57-11-4
titanium dioxide	13463-67-7
triacetin	102-76-1

### 3. HAZARDS IDENTIFICATION

#### Emergency Overview

Contact with broken tablets may result in skin, eye, and respiratory tract irritation. Dusts may form explosive mixtures in air.

#### HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe \* = Chronic hazard

#### Fire and Explosion Environment

Dusts may present an explosion hazard

#### Environment

Component Analysis - Ecotoxicity - Aquatic Toxicity

#### Eye Contact

None anticipated under normal product use conditions. Exposure to dusts from broken tablets may cause irritation.

#### Skin Contact

None anticipated under normal product use conditions. Prolonged skin exposure to dusts from broken tablets may cause irritation.

#### Inhalation

None anticipated under normal product use conditions. Exposure to dusts from broken tablets may cause respiratory tract irritation.

#### Ingestion

None anticipated under normal product use conditions. Avoid occupational ingestion.

### 4. FIRST- AID MEASURES

#### Eye Contact

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

#### Skin Contact

In the event of occupational skin contact, wash contaminated area thoroughly.

#### Inhalation

Move person to non-contaminated air. Call a physician if symptoms develop or persist.

#### Ingestion

In the event of occupational ingestion, seek medical advice. Induction of vomiting is not a recommended first-aid procedure.

#### Notes to a Physician

Treatment should be symptomatic.

### 5. FIRE- FIGHTING MEASURES

#### Specific Dangers :

Dusts may present an explosion hazard.

Extinguisher Type :

Use extinguishing media suitable for surrounding fire i.e. Water fog/spray.

Protection Measures :

Breathing apparatus for large/established/smoky fires.

## **6. ACCIDENTAL RELEASE MEASURES**

See also Sections 8 and 13

Personal Precautions:

Not considered necessary in normal consumer use.

Environmental Precautions:

Avoid contaminating drains. Dispose of in accordance with local regulations.

Methods for Cleaning Up:

Sweep up and place in an appropriate closed container. Avoid creation of dusty conditions. Clean up residual material by washing area with water.

## **7. HANDLING AND STORAGE**

Handling

Wash hands thoroughly after handling. Avoid breaking or crushing tablets.

Storage

The following requirements are in place for shipping and distribution (they may be different to those on the pack which provide guidance for long term storage by the consumer):

Protect from direct sunlight. Long term average storage temperature 20°C-25°C (68-77°F). Avoid extremes of temperature

Incompatible Products :

Oxides of carbon.

Packaging Materials:

Blister pack; Cardboard Carton

## **8. EXPOSURE CONTROL AND PERSONAL PROTECTION**

See also Section 7

Occupational Exposure Limits

None established

Engineering Controls

Control the airborne concentrations below the exposure limits. Use only with adequate ventilation.

#### Personal Protective Equipment

**Personal Protective Equipment: Eyes/Face**

None required under anticipated product use conditions.

**Personal Protective Equipment: Skin**

None required under anticipated product use conditions.

**Personal Protective Equipment: Respiratory**

None required under anticipated product use conditions.

**Personal Protective Equipment: General**

Eye wash fountain and emergency showers are recommended.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**MUCINEX SINUS-MAX DAY MAXIMUM STRENGTH (ITEM 0390598)**

<b>Appearance:</b>	Orange colour tablets	<b>Odour:</b>	None
<b>Physical State:</b>	Solid	<b>pH:</b>	ND
<b>Vapour Pressure:</b>	ND	<b>Vapour Density:</b>	ND
<b>Boiling Point:</b>	ND	<b>Melting Point:</b>	ND
<b>Solubility (H<sub>2</sub>O):</b>	ND	<b>Specific Gravity:</b>	ND
<b>Evaporation Rate:</b>	ND	<b>VOC:</b>	ND
<b>Octanol/H<sub>2</sub>O Coeff.:</b>	ND	<b>Flash Point:</b>	ND
<b>Flash Point Method:</b>	ND	<b>Upper Flammability Limit (UFL):</b>	ND
<b>Lower Flammability Limit (LFL):</b>	ND	<b>Burning Rate:</b>	ND
<b>Auto Ignition:</b>	ND		

**MUCINEX SINUS-MAX NIGHT MAXIMUM STRENGTH (ITEM 8054601)**

<b>Appearance:</b>	Blue colour tablets	<b>Odour:</b>	None
<b>Physical State:</b>	Solid	<b>pH:</b>	ND
<b>Vapour Pressure:</b>	ND	<b>Vapour Density:</b>	ND
<b>Boiling Point:</b>	ND	<b>Melting Point:</b>	ND
<b>Solubility (H<sub>2</sub>O):</b>	ND	<b>Specific Gravity:</b>	ND
<b>Evaporation Rate:</b>	ND	<b>VOC:</b>	ND
<b>Octanol/H<sub>2</sub>O Coeff.:</b>	ND	<b>Flash Point:</b>	ND
<b>Flash Point Method:</b>	ND	<b>Upper Flammability Limit (UFL):</b>	ND
<b>Lower Flammability Limit (LFL):</b>	ND	<b>Burning Rate:</b>	ND
<b>Auto Ignition:</b>	ND		

## 10. STABILITY AND REACTIVITY

#### Conditions to Avoid

None for normal handling of this product.

#### Materials to Avoid

Oxidising materials.

#### Hazardous Decomposition Products

Oxides of carbon may be evolved if product is involved in a fire.

## 11. TOXICOLOGICAL INFORMATION

### Acute Dose Effects

#### **A: General Product Information**

No information available for the product.

#### **B: Component Analysis - LD50/LC50**

##### **Guaifenesin (93-14-1)**

Oral LD50 Rat: 1510 mg/kg

##### **Paracetamol (UK) or Acetaminophen (USA) (103-90-2)**

Oral Rat LD50: 2404 mg/kg

IPR-Rat LD50: 1205 mg/kg

IPR-Mouse LD50: 367 mg/kg

##### **Phenylephrine Hydrochloride (61-76-1)**

LD50 Oral Mouse: 120 mg/kg

LD50 Oral Rat: 350 mg/kg

##### **Diphenhydramine Hydrochloride (147-24-0)**

LD50 Oral Mouse: 164mg/kg

LD50 Oral Rat: 500mg/kg

##### **Cellulose (9004-34-6)**

Inhalation LC50 Rat: >5800 mg/m<sup>3</sup>/4H;

Oral LD50 Rat:>5 g/kg;

Dermal LD50 Rabbit:>2 g/kg

##### **Hypromellose (9004-65-3)**

LD50 Intraperitoneal Rat: 5200mg/kg

##### **Titanium Dioxide (13463-67-7)**

LD Intratracheal Rat: >100ug/kg

##### **Polydextrose (68424-04-4)**

TDLo Oral Rat: 60g/kg

##### **Amorphous Silicon Dioxide (7631-86-9)**

LD50 Oral Rat: >5110mg/kg;

LD50 Dermal Rabbit: 5000mg/kg

##### **Croscarmellose Sodium (78411-65-7)**

LD50 Oral Rat: 15000 - 27000mg/kg

### Carcinogenicity

#### **A: General Product Information**

No information available for the product.

**B: Component Carcinogenicity**

**Acetaminophen**  
Possible carcinogen

**Titanium Dioxide**  
Class 2B Carcinogen via inhalation

**12. ECOLOGICAL INFORMATION****Ecotoxicity**

**A: General Product Information**  
No data available for this product.

**B: Component Analysis - Ecotoxicity - Aquatic Toxicity**

**Amorphous Silicon Dioxide**  
LC50 (96hr) Brachydanio rerio: 10000mg/L

**Titanium Dioxide**  
Acute EC50 (72hr) Algae: 35.9mg/L Fresh Water

Acute EC50 (72hr) Algae: 5.83mg/L Fresh Water

Acute EC50 (48hr) Daphnia: >1000000ug/L Fresh Water

Acute EC50 (48hr) Daphnia Juvenile: 5.5ppm Fresh Water

Acute LC50 (96hr) Mummichog: >1000000ug/L Fresh Water

Chronic NOEC (72hr) Algae: 95mg/L Fresh Water

Chronic NOEC (72hr) Algae: 10.1mg/L Fresh Water

Chronic NOEC (72hr) Algae: 0.984mg/L Fresh Water

Chronic NOEC (48hr) Daphnia: 500ppm Fresh Water

Chronic NOEC (48hr) Daphnia Juvenile: 1ppm Fresh Water

**Polyethylene Glycol**  
Acute LC50 (96hr) Rainbow Trout: >20000000ug/L Fresh Water  
Acute LC50 (96hr) Atlantic Salmon: >1000000ug/L Fresh Water

**13. DISPOSAL CONSIDERATIONS**

Treatment, storage, transportation and disposal must be in accordance with applicable federal, state/provincial and local regulations. Do not flush to surface water or sanitary sewer system.

Consumer Instructions

Containers may be disposed of in normal household waste systems.

Bulk Quantities/Unsold Stock

Bulk quantities should be disposed of in accordance with local authority requirements.

**14. TRANSPORT INFORMATION**

UN Number: Not applicable  
International Transport: Not classified as hazardous for transport.  
D.O.T Not regulated

National transport regulations may apply.

The supply chain temperature limits provided in Section 7 must be adhered to during transportation

## 15. REGULATORY INFORMATION

United States: This product is regulated by the Food, Drug and Cosmetic Act.

## 16. OTHER INFORMATION

### Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial and local laws. All raw material ingredients meet or exceed United States Pharmacopeia requirements.

### Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration, NJTSR = New Jersey Trade Secret Registry.

### Where Used

#### Where Used

#### Customer Product Bill of Material

#### Formulation Bill of Material

8054601 : FIL,MUCNX,LNK NIGHT

### History

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<b>Co-Author:</b>	Emma Proctor/EUR/R_B	
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