



# Material Safety Data Sheet

ANSI Format

## Dristan Nasal Products

Preparation Date 19-Sep-2007

Revision Date Not applicable

Revision Number Not applicable

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name** Dristan Nasal Products  
**Common Name** Not available  
**Chemical Name** Not applicable  
**Synonyms** Oxymetazoline HCl, Dristan 12 Hour Nasal Spray, Dristan Nasal Spray, Dristan Long Lasting Nasal Mist, Dristan Metholated Long Lasting Nasal Spray, Dristan Nasal Mist  
**Product Use** Pharmaceutical product  
**Classification** Topical vasoconstrictor  
**Supplier** Wyeth  
P.O. Box 8299  
Philadelphia, PA 19101 USA.  
Telephone: 1-610-688-4400

**Emergency Telephone Number** Chemtrec USA, Puerto Rico, Canada 1-800-424-9300  
Chemtrec International 1-703-527-3887

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

**Appearance** Pharmaceutical Liquid **Physical State** Liquid **Odor** Not available

#### Potential Physical Hazards

None known

#### Potential Health Effects

**Eyes**  
**Skin**

Irritating to eyes.

The most common effects may include blurred vision; fast, irregular, or pounding heartbeat; headache; dizziness; drowsiness; light-headedness; high blood pressure; nervousness; trembling; sleep disturbances; and weakness. burning, dryness or stinging of nasal mucosa, increase in nasal discharge, and sneezing may also occur.

Please see Product Insert for further information.

**Inhalation**  
**Ingestion**

Not available

Not available

**Therapeutic Target Organ(s)**

Upper respiratory tract.

Not listed by OSHA, NTP or IARC.

#### Potential Environmental Effects

There is no known ecological information for this product.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Common Name	CAS-No	Composition
Oxymetazoline HCl	2315-02-8	0.05%
Benzyl Alcohol	100-51-6	0.5%
Phenylephrine HCl	61-76-7	0-0.5%
Pheniramine HCl	25332-09-6	0-0.2%
Inactive Ingredients	Not applicable	Remainder

**4. FIRST AID MEASURES**

<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
<b>Inhalation</b>	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
<b>Ingestion</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

**5. FIRE-FIGHTING MEASURES**

<b>Flammable Properties</b>	None.
<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	Use water spray, foam, dry chemical or carbon dioxide.
<b>Unsuitable Extinguishing Media</b>	Do NOT use water jet.
<b>Fire Fighting</b>	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
<b>Hazardous Combustion Products</b>	Carbon oxides, nitrogen oxides.
<b>Protective Equipment and Precautions for Firefighters</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

**6. ACCIDENTAL RELEASE MEASURES**

<b>Personal Precautions</b>	Refer to protective measures listed in Sections 7 and 8.
<b>Environmental Precautions</b>	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
<b>Methods for Containment</b>	Not available
<b>Methods for Cleaning up</b>	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

## 7. HANDLING AND STORAGE

<b>Handling</b>	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
<b>Storage</b>	No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Common Name</b>	<b>Exposure Guideline</b>
Inactive Ingredients	250 mg/m <sup>3</sup>
Oxymetazoline HCl	1 mcg/m <sup>3</sup>
Benzyl Alcohol	15 ppm (Germany)
Phenylephrine HCl	40 mcg/m <sup>3</sup>
Pheniramine HCl	75 mcg/m <sup>3</sup>
<b>Engineering Controls</b>	No special precautions required.
<b>Personal Protective Equipment</b>	
<b>Eye/Face Protection</b>	Avoid contact with skin and eyes. Provide eye protection based on a risk assessment.
<b>Skin Protection</b>	For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use.
<b>Respiratory Protection</b>	No personal respiratory protective equipment normally required.
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Pharmaceutical Liquid	<b>Physical State</b>	Liquid
<b>Color</b>	Clear, colorless to slightly yellow	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>pH</b>	Not available		
<b>Specific Gravity</b>	Not available	<b>Water Solubility</b>	Soluble in water
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not available
<b>Partition Coefficient (n-octanol/water)</b>	Not available	<b>Vapor Density</b>	Not available
<b>Vapor Pressure</b>	Not applicable		
<b>Boiling Point</b>	Not available	<b>Autoignition Temperature</b>	Not applicable
<b>Flash Point</b>	Not available	<b>Method</b>	None
<b>Melting Point</b>	Not applicable		
<b>Flammability Limits in Air</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	
<b>Explosion Limits</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	

## 10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	None under normal use.
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	No data available
Possibility of Hazardous Reactions	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

#### Inactive Ingredients

LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

#### Oxymetazoline HCl

LD50 Oral	680 mcg/kg rats, 4700 mcg/kg mice
Acute Dermal Irritation	No data available
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

#### Benzyl Alcohol

LD50 Oral	No data available
Acute Dermal Irritation	Not available
Primary Eye Irritation	Not available
Sensitization	Not applicable

#### Phenylephrine HCl

LD50 Oral	350 mg/kg rats, 1400 mg/kg mice
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	No data available
Sensitization	No data available

#### Pheniramine HCl

LD50 Oral	No data available
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

### Multiple Dose Toxicity

#### Oxymetazoline HCl

No Toxicologic Effect  
Dose/Species/Study Length: Not applicable

Pheniramine HCl  
No Toxicologic Effect  
Dose/Species/Study Length: No data available

#### Maximum Tolerated Dose (MTD), Oral

Oxymetazoline HCl  
Carcinogenicity No carcinogenicity studies have been performed.  
Genetic Toxicity No mutagenicity studies have been performed.  
Reproductive Toxicity Animal studies to evaluate effects on fertility have not been conducted.  
Developmental Toxicity No teratogenic effects were observed in mice, rabbits, or hamsters.

Benzyl Alcohol  
Carcinogenicity No studies to assess the carcinogenic potential have been performed.  
Genetic Toxicity Not genotoxic in vitro or in vivo  
Reproductive Toxicity Not reprotoxic.  
Developmental Toxicity Not developmentally toxic.

Phenylephrine HCl  
Carcinogenicity Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.  
Genetic Toxicity No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.  
Reproductive Toxicity No data available  
Developmental Toxicity No data available

Pheniramine HCl  
Carcinogenicity No data available  
Genetic Toxicity No data available  
Reproductive Toxicity No data available  
Developmental Toxicity No data available

Oxymetazoline HCl  
Target Organ(s) of Toxicity No data available

Benzyl Alcohol  
Target Organ(s) of Toxicity No data available

Phenylephrine HCl  
Target Organ(s) of Toxicity No data available

Pheniramine HCl  
Target Organ(s) of Toxicity No data available

## 12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Ecotoxicity Not available

## 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

## 14. TRANSPORT INFORMATION

Transport Information Not classified as dangerous in the meaning of transport regulations.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

## 15. REGULATORY INFORMATION

### USA

#### Federal Regulations

#### **OSHA Regulatory Status**

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

#### **SARA 311/312 Hazardous Categorization**

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

### State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **Canada**

Not classified

#### **WHMIS Hazard Class**

Non-controlled

#### **European Union**

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

## **16. OTHER INFORMATION**

#### **Prepared By**

Wyeth Department of Environment, Health & Safety

#### **Format**

This MSDS was prepared in accordance with ANSI Z400.1-2004.

#### **List of References**

ToxNet, Toxicology Data Network, US National Library of Medicine

#### **Revision Summary**

Updated for Canadian Products

#### **Disclaimer:**

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**End of MSDS**