1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Dristan Nasal Products
Common Name: Not available
Chemical Name: Not applicable
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

Potential Physical Hazards: None known

Potential Health Effects:
- Eyes: 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.
- Skin
- Inhalation: Not available
- Ingestion: 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

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxymetazoline HCl</td>
<td>2315-02-8</td>
<td>0.05%</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>0.5%</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>61-76-7</td>
<td>0-0.5%</td>
</tr>
<tr>
<td>Pheniramine HCl</td>
<td>25332-09-6</td>
<td>0-0.2%</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

Skin Contact
Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation
Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion
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

Flammable Properties
None.

Extinguishing Media

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Unsuitable Extinguishing Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use water spray, foam, dry chemical or carbon dioxide.</td>
<td>Do NOT use water jet.</td>
</tr>
</tbody>
</table>

Fire Fighting
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.

Hazardous Combustion Products
Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters
In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions
Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment
Not available

Methods for Cleaning up
Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.
7. HANDLING AND STORAGE

Handling

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.

Storage

No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name

Exposure Guideline

Inactive Ingredients

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Exposure Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxymetazoline HCl</td>
<td>250 mg/m³</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>1 mcg/m³</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>15 ppm (Germany)</td>
</tr>
<tr>
<td>Pheniramine HCl</td>
<td>40 mcg/m³</td>
</tr>
</tbody>
</table>

Engineering Controls

No special precautions required.

Personal Protective Equipment

Eye/face Protection

Avoid contact with skin and eyes. Provide eye protection based on a risk assessment.

Skin Protection

For prolonged or repeated exposure use protective gloves. No special protective clothing required under typical conditions of use.

Respiratory Protection

No personal respiratory protective equipment normally required.

General Hygiene

When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other

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

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

No mutagenicity studies have been performed.

No data available.

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.

Developmental Toxicity

No data available.

Reproductive Toxicity

Animal studies to evaluate effects on fertility have not been conducted.

Pheniramine HCl

No Toxicologic Effect

Dose/Species/Study Length: No data available

Phenylephrine HCl

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

Pheniramine HCl

Target Organ(s) of Toxicity

No data available

Pheniramine HCl

Target Organ(s) of Toxicity

No data available

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

Pheniramine HCl

Target Organ(s) of Toxicity

No data available

Revision Date Not applicable

Dristan Nasal Products

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

Benzyl Alcohol

No data available

Oxymetazoline HCl

Carcinogenicity

No data available

Genetic Toxicity

No data available

Reproductive Toxicity

No data available

Developmental Toxicity

No data available

Pheniramine HCl

No Toxicologic Effect

Dose/Species/Study Length: No data available

Phenylephrine HCl

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:
The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. **NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS.** Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS