1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Dristan Solid Products  
Common Name: Not available  
Chemical Name: Not applicable  
Synonyms: Dristan Caplets, Dristan Non-Drowsy Caplets, Dristan Tablets, Dristan Multi-Symptom Cold Tablets, Dristan Sinus Caplets, Dristan Extra Strength, Dristan Extra Strength Non-Drowsy  
Product Use: Pharmaceutical product  
Classification: Fever Reducer, Nasal Decongestant, Antihistamine  
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.

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Pharmaceutical Tablet or Caplet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
</tbody>
</table>

Potential Physical Hazards: Powders and solids are presumed to be combustible.

Potential Health Effects:

| Eyes        | Not available               |
| Skin        | Not available               |
| Inhalation  | Not available               |
| Ingestion   | The most common effects may include sleep disturbances, drowsiness, dizziness and excitability. May impair ability when driving a motor vehicle or operating machinery. May cause harm to the unborn child. |
| Therapeutic Target Organ(s) | Central nervous system |
| — | Not listed by OSHA, NTP or IARC. |

Potential Environmental Effects: See Section 12.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylsalicylate Acid</td>
<td>50-78-2</td>
<td>0-325 mg/tablet</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>103-90-2</td>
<td>0-500 mg/tablet</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>15687-27-1</td>
<td>0-200 mg/tablet</td>
</tr>
<tr>
<td>Pseudoephedrine HCl</td>
<td>345-78-8</td>
<td>0-30 mg/tablet</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>61-76-7</td>
<td>0-5 mg/tablet</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>113-92-8</td>
<td>0-2 mg/tablet</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
<tr>
<td>Caffeine</td>
<td>58-08-2</td>
<td>0-16.2 mg/tablet</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

**Eye Contact**
In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes 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.

**Aggravated Medical Conditions**
Not available

5. FIRE-FIGHTING MEASURES

**Flammable Properties**
Presumed to be a combustible particulate solid.

**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. 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

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Exposure Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylsalicylate Acid</td>
<td>750 mcg/m³</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>2000 mcg/m³</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>2000 mcg/m³</td>
</tr>
<tr>
<td>Pseudoephedrine HCl</td>
<td>200 mcg/m³</td>
</tr>
<tr>
<td>Caffeine</td>
<td>500 mcg/m³</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>40 mcg/m³</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>10 mcg/m³</td>
</tr>
</tbody>
</table>

Engineering Controls

Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

| Eye/face Protection       | Provide eye protection based on risk assessment. |
| Skin Protection           | Wear nitrile or latex gloves. Wear protective garment. |
| Respiratory Protection    | Base respirator selection on a risk assessment. |
| General Hygiene Considerations | 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>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical Tablet or Caplet</td>
</tr>
<tr>
<td>Color</td>
<td>Various</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 applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient</td>
<td>Not available</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Chemical Stability
Stable at room temperature.

Conditions to Avoid
No data available

Materials to Avoid
No materials to be especially mentioned.

Hazardous Decomposition Products
None under normal use.

Possibility of Hazardous Reactions
None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Acetylsalicylate Acid
LD50 Oral 1460 mg/kg rats, 1100 mg/kg mice, 1010 mg/kg rabbits
Acute Dermal Irritation 7940 mg/kg rabbits, slightly irritating to rabbit skin.
Primary Eye Irritation Irritating to rabbit eyes.
Sensitization Not a dermal sensitizer in guinea pigs.

Acetaminophen
LD50 Oral 2404 mg/kg rats
Acute Dermal Irritation No data available
Primary Eye Irritation No data available
Sensitization No data available

Ibuprofen
LD50 Oral 625 mg/kg rats
Acute Dermal Irritation No data available
Primary Eye Irritation No data available
Sensitization No data available

Pseudoephedrine HCl
LD50 Oral 371 mg/kg mice
Acute Dermal Irritation No data available
Primary Eye Irritation No data available
Sensitization No data available

Caffeine
LD50 Oral 192 mg/kg rats, 125 mg/kg mice
Acute Dermal Irritation > 2000 mg/kg rats
### Multiple Dose Toxicity

<table>
<thead>
<tr>
<th>Compound</th>
<th>Dose/Species/Study Length</th>
<th>Toxicologic Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine HCl</td>
<td></td>
<td>Maximum Tolerated Dose (MTD), Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 Oral: 350 mg/kg rats, 1400 mg/kg mice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Dermal Irritation: Not irritating to rabbit skin.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Primary Eye Irritation: No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sensitization: No data available</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td></td>
<td>Maximum Tolerated Dose (MTD), Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 Oral: 118-680 mg/kg rats, 121 mg/kg mice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Dermal Irritation: No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Primary Eye Irritation: No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sensitization: No data available</td>
</tr>
</tbody>
</table>

### Acetylsalicylate Acid

- **Carcinogenicity:** See Carcinogenicity
- **Genetic Toxicity:** AMES Test: Negative: Nonmutagenic.
- **Reproductive Toxicity:** See Developmental Toxicity.
- **Developmental Toxicity:** Fetotoxic and a teratogen in rats, mice, dogs, cats and monkeys at high doses.

### Ibuprofen

- **Carcinogenicity:** Not available
- **Genetic Toxicity:** Not mutagenic in AMES Test.
- **Reproductive Toxicity:** Testicular atrophy and inhibition of spermatogenesis was seen in animal studies at high dose levels. Relevance to humans is not known.
- **Developmental Toxicity:** See Reproductive Toxicity.
Ibuprofen
- **Carcinogenicity**: Carcinogenic studies in mice and rats were negative.
- **Genetic Toxicity**: Non-mutagenic in *in vivo* studies.
- **Reproductive Toxicity**: Reproduction studies in rats and mice did not reveal any evidence of impaired fertility or embryotoxicity.
- **Developmental Toxicity**: Reproduction studies in rats and mice did not reveal any teratogenic effects.

Pseudoephedrine HCl
- **Carcinogenicity**: No data available
- **Genetic Toxicity**: No data available
- **Reproductive Toxicity**: No data available
- **Developmental Toxicity**: No data available

Caffeine
- **Carcinogenicity**: In a 2-year study in rats and mice, no evidence of carcinogenic potential was observed.
- **Genetic Toxicity**: Evidence of Genotoxicity was observed in a battery of studies.
- **Reproductive Toxicity**: Studies in monkeys have resulted in reduced fetal weight, stillbirths, and miscarriages.
- **Developmental Toxicity**: Teratogenic effects were reported in both rats and mice at high doses (> 40 mg/kg/day). Digital defects, cleft palate, extra embryonic structures, and urogenital and musculoskeletal abnormalities were induced. Other findings in animal studies include inhibition of neurogenesis in the mouse embryo; reduced cerebral weight and cardiovascular, lens and thymic changes in rats.

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

Chlorpheniramine Maleate
- **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**: Animal studies to evaluate effects on fertility have not been conducted.
- **Developmental Toxicity**: No teratogenic effects were observed in mice.

Acetylsalicylate Acid
- **Target Organ(s) of Toxicity**: No data available

Acetaminophen
- **Target Organ(s) of Toxicity**: No data available

Ibuprofen
- **Target Organ(s) of Toxicity**: No data available

Pseudoephedrine HCl
- **Target Organ(s) of Toxicity**: No data available

Caffeine
- **Target Organ(s) of Toxicity**: No data available

Phenylephrine HCl
| Chlorpheniramine Maleate | Target Organ(s) of Toxicity | No data available |
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Acetylsalicylate Acid
- **Mobility**: Not available
- **Biodegradability**: Readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Bioaccumulation is unlikely.

Acetaminophen
- **Mobility**: Not available
- **Biodegradability**: Not available
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

Ibuprofen
- **Mobility**: Not available
- **Biodegradability**: Not available
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

Pseudoephedrine HCl
- **Mobility**: Not available
- **Biodegradability**: Moderately biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

Caffeine
- **Mobility**: Not available
- **Biodegradability**: Readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Bioaccumulation is unlikely.

Phenylephrine HCl
- **Mobility**: Not available
- **Biodegradability**: Not available
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

Chlorpheniramine Maleate
- **Mobility**: Not available
- **Biodegradability**: Not available
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

Ecotoxicity

Acetylsalicylate Acid
- **Microorganisms**: Not available
13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

Transport Information
This material is not classified as hazardous for transport.

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
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
<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>Yes</td>
</tr>
<tr>
<td>Fire Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

This product does not contain any HAPs.

State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals:

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylsalicylate Acid</td>
<td>50-78-2</td>
<td>Developmental Female Reproductive</td>
</tr>
</tbody>
</table>

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
Product Profiles

Revision Summary
Changes to 8.

Disclaimer:
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End of MSDS