1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Robitussin - DAC
Common Name: Not applicable
Chemical Name: Not applicable
Synonyms: Robitussin- DAC
Product Use: Pharmaceutical product
Classification: Analgesic, Antihistamine, Antitussive, Decongestant, Expectorant, Central Nervous System Agent
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: Slight fire hazard.

Potential Health Effects:
- Eyes: May cause irritation.
- Skin: Not available
- Inhalation: Not available
- Ingestion: The most common effects may include allergy, drowsiness, nervousness, excitability, dizziness, sleeplessness, and constipation. May impair ability when driving a motor vehicle or operating machinery.
  - May cause harm to the unborn child. May cause harm to breastfed babies.
  - Please see Patient Package Insert for further information.

  Therapeutic Target Organ(s): Nervous system, respiratory system.

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>Pseudoephedrine HCl</td>
<td>345-78-8</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Guaifenesin</td>
<td>93-14-1</td>
<td>&gt;1%</td>
</tr>
<tr>
<td>Codeine Phosphate</td>
<td>52-28-8</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>64-17-5</td>
<td>&gt;1%</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.

### 5. FIRE-FIGHTING MEASURES

**Flammable Properties**

Slight fire hazard.

**Extinguishing Media**

- **Suitable Extinguishing Media**: Use alcohol-resistant foam, dry chemical or carbon dioxide.
- **Unsuitable Extinguishing Media**: Do NOT use water jet.

**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
--- | ---
Guaifenesin | 3000 mcg/m³
Codeine Phosphate | 200 mcg/m³
Pseudoephedrine HCl | 200 mcg/m³
Ethyl Alcohol | 1000 ppm

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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Red</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 (n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point</td>
<td>&gt;110°C</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>Water Solubility</td>
<td>Not available</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not available</td>
</tr>
<tr>
<td>Autoignition Temperature Method</td>
<td>Not available</td>
</tr>
<tr>
<td>Autoignition Temperature</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
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

Guaifenesin
LD50 Oral 1510 mg/kg rats
Acute Dermal Irritation Not applicable
Primary Eye Irritation Not applicable
Sensitization Not applicable

Codeine Phosphate
LD50 Oral 427 mg/kg rats, 250 mg/kg mice
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

Ethyl Alcohol
LD50 Oral 7060 mg/kg rats, 8300 mg/kg mice
Acute Dermal Irritation Moderate irritation effects in rabbits.
Primary Eye Irritation Severe irritation effects in rabbits.
Sensitization Not applicable

Multiple Dose Toxicity

Guaifenesin
No Toxicologic Effect No data available
Dose/Species/Study Length:

Pseudoephedrine HCl
No Toxicologic Effect No data available
Dose/Species/Study Length:
Ethyl Alcohol
- No Toxicologic Effect
- Dose/Species/Study Length: Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.

Maximum Tolerated Dose (MTD), Oral

Guaifenesin
- Carcinogenicity: No studies to assess the carcinogenic potential have been performed.
- Genetic Toxicity: No evidence of mutagenicity was observed in a battery of \textit{in vitro} and \textit{in vivo} assays.
- Reproductive Toxicity: Animal studies to evaluate effects on fertility have not been conducted.
- Developmental Toxicity: Studies to evaluate the teratogenic potential have not been performed.

Codeine Phosphate
- Carcinogenicity: Long-term studies in rats and mice revealed no evidence of carcinogenicity.
- Genetic Toxicity: No evidence of mutagenicity was observed in a battery of \textit{in vitro} and \textit{in vivo} assays.
- Reproductive Toxicity: At a maternally toxic dose of 120 mg/kg/day, embryo resorptions at the time of implantation were reported. In pregnant mice, a single dose of 100 mg/kg resulted in delayed ossification of offspring.
- Developmental Toxicity: No teratogenic effects were observed in rats or rabbits.

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

Ethyl Alcohol
- Carcinogenicity: No data available
- Genetic Toxicity: May cause genetic changes.
- Reproductive Toxicity: See Developmental Toxicity.
- Developmental Toxicity: Repeated exposure may cause spontaneous abortions, as well as birth defects and other developmental problems (fetal alcohol syndrome).

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

Codeine Phosphate
- Target Organ(s) of Toxicity: No data available

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

Ethyl Alcohol
- Target Organ(s) of Toxicity: No data available
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

<table>
<thead>
<tr>
<th>Pseudoephedrine HCl</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>Not available</td>
</tr>
<tr>
<td>Biodegradability</td>
<td>Moderately biodegradable.</td>
</tr>
<tr>
<td>Stability in Water</td>
<td>Not available</td>
</tr>
<tr>
<td>Bioaccumulation</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Ecotoxicity

<table>
<thead>
<tr>
<th>Ethanol</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>May adsorb on sludge or particles in natural waters.</td>
</tr>
<tr>
<td>Biodegradability</td>
<td>Not available</td>
</tr>
<tr>
<td>Stability in Water</td>
<td>Hydrolyses in water.</td>
</tr>
<tr>
<td>Bioaccumulation</td>
<td>Bioaccumulative potential.</td>
</tr>
</tbody>
</table>

Pseudoephedrine HCl

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>Not available</td>
</tr>
<tr>
<td>Daphnia</td>
<td>Not available</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50/96h/golden orfe = 460-1000 mg/l</td>
</tr>
</tbody>
</table>

Ethanol

<table>
<thead>
<tr>
<th>Microorganisms</th>
<th>EC50 &gt; Aqueous solubility limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algae</td>
<td>EC50/72h/algae = 0.063 mg/l, NOEC = 0.015 mg/l</td>
</tr>
<tr>
<td>Daphnia</td>
<td>EC50/48h/daphnia &gt; Aqueous solubility limit, NOEC = Aqueous solubility limit</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50/96h/fathead minnow &gt; Aqueous solubility limit, NOEC &gt; Aqueous solubility limit</td>
</tr>
</tbody>
</table>

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method

Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information

<table>
<thead>
<tr>
<th>U.S. Department of Transport (DOT)</th>
<th>Not regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canadian Transport of Dangerous Goods (TDG)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>International Civil Aviation Organization (ICAO)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>International Air Transport Association (IATA)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Transport of Dangerous Goods by Rail (RID)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Transport of Dangerous Goods by Road (ADR)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Transportation of Dangerous Goods via Inland Waterways (ADN)</td>
<td>Not regulated</td>
</tr>
</tbody>
</table>
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></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire Hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sudden Release of Pressure Hazard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td></td>
<td></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>Codeine Phosphate</td>
<td>52-28-8</td>
<td>Developmental</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
ToxNet, Toxicology Data Network, US National Library of Medicine

Revision Summary
Updated for Canadian Products, Changes to Section 2 and 11

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End of MSDS