1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Primatene Tablets
Common Name: Not applicable
Chemical Name: Not applicable
Synonyms: Not available
Product Use: Pharmaceutical product
Classification: Adrenergic Agent
Supplier: Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-686-4400

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

2. HAZARDS IDENTIFICATION

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

Potential Health Effects:

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical State</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Tablet</td>
<td>Solid</td>
<td>Not available</td>
</tr>
</tbody>
</table>

- Eyes: Not available
- Skin: Not available
- Inhalation: Not available
- Ingestion: The most common effects may include nervousness, sleeplessness, rapid heartbeat, tremor, and seizure.

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>Ephedrine HCl</td>
<td>50-98-6</td>
<td>12.5 mg/tablet</td>
</tr>
<tr>
<td>Guaifenesin</td>
<td>93-14-1</td>
<td>200 mg/tablet</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 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
Presumed to be a combustible particulate solid.

Extinguishing Media

- Suitable Extinguishing Media: Use water spray, 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

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
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 Tablet</td>
</tr>
<tr>
<td>Color</td>
<td>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 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>Not available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</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>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</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>
<tr>
<td>Autoignition Temperature Method</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point in Air</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper Flammability Limits in Air</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower Flammability Limits in Air</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper Explosion Limits</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower Explosion Limits</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Chemical Stability</th>
<th>Stable at room temperature.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No materials to be especially mentioned.</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>None under normal use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>None under normal use.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

**Ephedrine HCl**
- **LD$_50$ Oral**: 600 mg/kg rats, 400 mg/kg mice
- **Acute Dermal Irritation**: >2000 mg/kg rats
  - Not irritating to rabbit skin.
- **Primary Eye Irritation**: Not irritating to rabbit eyes.
- **Sensitization**: No data available

**Guaifenesin**
- **LD$_50$ Oral**: 1510 mg/kg rats
- **Acute Dermal Irritation**: Not applicable
- **Primary Eye Irritation**: Not applicable
- **Sensitization**: Not applicable

### Multiple Dose Toxicity

**Ephedrine HCl**
- No Toxicologic Effect
  - No data available

**Guaifenesin**
- No Toxicologic Effect
  - No data available

### Maximum Tolerated Dose (MTD), Oral

**Ephedrine HCl**
- **Carcinogenicity**: No studies to assess the carcinogenic potential have been performed. Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in
- **Genetic Toxicity**: Tests on bacterial or mammalian cell cultures did not show mutagenic effects.
- **Reproductive Toxicity**: No data available
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Ephedrine HCl
- **Mobility**: Not available
- **Biodegradability**: Readily biodegradable (90 - 100% after 18 days)
- **Stability in Water**: Not available
- **Bioaccumulation**: Bioaccumulation is unlikely.

Ecotoxicity

Ephedrine HCl
- **Microorganisms**: EC50/17h/bacteria = 6400 mg/lh/bacteria = mg/l
- **Algae**: Not available
- **Daphnia**: Not available
- **Fish**: LC50/96h/golden orfe = 460 mg/l

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
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: Yes
- 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: See Patient Package Insert for more information.
Revision Summary: Not applicable

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End of MSDS