



**Primatene Mist**

Preparation Date 25-Jun-2007

Revision Date 02-May-2008

Revision Number 3

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name** Primatene Mist  
**Common Name** Not available  
**Chemical Name** Not applicable  
**Synonyms** Primatene Asthma Mist Inhaler, Epinephrin  
**Product Use** Pharmaceutical product  
**Classification** Adrenergic 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**

**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** Containers may rupture or explode if exposed to heat. Flammable liquid

**Potential Health Effects**

**Eyes** Irritating to eyes.  
**Skin** May cause irritation.  
**Inhalation** The most common effects may include increased blood pressure, nervousness, sleeplessness, rapid heartbeat, tremors, and seizure.

May cause harm to the unborn child. May cause harm to breastfed babies.

Please see Patient Package Insert for further information.

**Ingestion** Not available  
**Therapeutic Target Organ(s)** Nervous system, Respiratory system.

Not listed by OSHA, NTP or IARC.

**Potential Environmental Effects** Contains CFC 12, 114 - substances which harm public health and environment by destroying ozone in the upper atmosphere.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Epinephrine salts	Not applicable	0.22 mg/dose
Ethyl Alcohol	64-17-5	34%
Hydrochloric Acid (2N)	7647-01-0	1.104%
Dichlorofluoromethane (CFC 12)	75-43-4	24.914%
Dichlorotetrafluoroethane (CFC 114)	76-14-2	37.371%
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 for 15 minutes 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>	Flammable liquid. Vapors may cause flash fire or explosion..
<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. Contains CFC 12, 114, substances which harm public health and environment by destroying ozone in the upper atmosphere.
<b>Methods for Containment</b>	Kepp away from heat and sources of ignition.
<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>	Keep away from open flames, hot surfaces and sources of ignition

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Common Name</b>	<b>Exposure Guideline</b>
Hydrochloric Acid (2N)	Ceiling 2 ppm (ACGIH)
Dichlorofluoromethane (CFC 12)	10 ppm (ACGIH)
Dichlorotetrafluoroethane (CFC 114)	1000 ppm (ACGIH)
Ethyl Alcohol	1000 ppm
<b>Engineering Controls</b>	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.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Provide eye protection based on risk assessment..
<b>Skin Protection</b>	Wear nitrile or latex gloves. Wear protective garment.
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment..
<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>	Cream	<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>	Not available
<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 Method</b>	Not applicable
<b>Flash Point</b>	Not available		None
<b>Melting Point</b>	Not applicable		
<b>Flammability Limits in Air</b>	<b>Upper</b> Not available	<b>Lower</b> Not available	
<b>Explosion Limits</b>	<b>Upper</b> Not available	<b>Lower</b> Not available	

## 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable at room temperature.
<b>Conditions to Avoid</b>	Keep away from heat and sources of ignition.
<b>Materials to Avoid</b>	No materials to be especially mentioned.
<b>Hazardous Decomposition Products</b>	None under normal use.
<b>Possibility of Hazardous Reactions</b>	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Acute Toxicity

#### Ethyl Alcohol

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

#### Epinephrine salts

<b>LD50 Oral</b>	No data available
<b>Acute Dermal Irritation</b>	No data available
<b>Primary Eye Irritation</b>	No data available
<b>Sensitization</b>	No data available

### Multiple Dose Toxicity

#### Ethyl Alcohol

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.
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#### Epinephrine salts

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	No data available
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### Maximum Tolerated Dose (MTD), Oral

#### Ethyl Alcohol

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

#### Epinephrine salts

<b>Carcinogenicity</b>	No data available
<b>Genetic Toxicity</b>	No data available
<b>Reproductive Toxicity</b>	No data available

Developmental Toxicity No data available

**Ethyl Alcohol**

Target Organ(s) of Toxicity No data available

**Epinephrine salts**

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 No data available

## 14. TRANSPORT INFORMATION

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

**U.S. Department of Transport (DOT)**

Proper Shipping Name Consumer Commodity

Hazard Class ORM-D

UN-No Not assigned

Packing Group Not assigned

Canadian Transport of Dangerous Goods (TDG) Not regulated

International Civil Aviation Organization (ICAO) Not regulated

**International Air Transport Association (IATA)**

Proper Shipping Name Consumer Commodity

Hazard Class 9

UN-No ID 8000

Packing Group Not assigned (treat as PG II)

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

USAFederal 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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:

Common Name	CAS-No	Concentration
Dichlorofluoromethane (CFC 12)	75-43-4	> 1
Dichlorotetrafluoroethane (CFC 114)	76-14-2	> 1

**SARA 311/312 Hazardous Categorization**

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

This product does not contain any HAPs..

**State Regulations****California Proposition 65**

Ethyl alcohol (ethanol) is listed.

**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.

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**16. OTHER INFORMATION**

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with ANSI Z400.1-2004.
<b>List of References</b>	See Patient Package Insert for more information.
<b>Revision Summary</b>	Changes to Section 3, 13

## Disclaimer:

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**End of MSDS**