



Material Safety Data Sheet

ANSI Format

Primatene Tablets

Preparation Date 26-Jan-2007

Revision Date Not applicable

Revision Number Not applicable

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: 1-610-688-4400

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 Tablet **Physical State** Solid **Odor** Not available

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 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.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Ephedrine HCl	50-98-6	12.5 mg/tablet
Guaifenesin	93-14-1	200 mg/tablet
Inactive Ingredients	Not applicable	Remainder

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 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

Appearance	Pharmaceutical Tablet	Physical State	Solid
Color	Yellow	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not available	Autoignition Temperature	Not available
Flash Point	Not available	Method	None
Melting Point	Not available		
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

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

Ephedrine HCl

LD50 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

LD50 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
Dose/Species/Study Length:	

Guaifenesin

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

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 carcinogenicity activity in
Genetic Toxicity	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.
Reproductive Toxicity	No data available

Developmental Toxicity	A dose-dependent increase in the frequency of cardiac anomalies, primarily ventricular septal defects, was reported among the offspring of rats treated during pregnancy with ephedrine in doses 1-420 times the human daily dose in a study that has only been published as an abstract. An increased frequency of malformations was reported among the offspring of pregnant rabbits treated with 17-33 times the human daily dose of ephedrine in combination with theophylline and phenobarbital.
Guaifenesin	
Carcinogenicity	No studies to assess the carcinogenic potential have been performed.
Genetic Toxicity	No studies to assess the mutagenic potential have been performed.
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.
Ephedrine HCl	
Target Organ(s) of Toxicity	No data available
Guaifenesin	
Target Organ(s) of 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.
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14. TRANSPORT INFORMATION

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