



**Dimetapp Liquid Products**

Preparation Date 21-Aug-2007

Revision Date 31-Mar-2008

Revision Number 5

**1. PRODUCT AND COMPANY IDENTIFICATION**

<b>Product Name</b>	Dimetapp Liquid Products
<b>Common Name</b>	Not applicable
<b>Chemical Name</b>	Not applicable
<b>Synonyms</b>	Dimetapp Cold & Allergy Elixir, Dimetapp DM Cold & Cough Elixir, Dimetapp Nighttime Flu, Dimetapp Decongestant Infant Drops, Dimetapp Decongestant Plus Cough Infant Drops, Dimetapp Long Acting Cough Plus Cold, Dimetapp Cold & Fever Suspension, Children's Dimetapp Nighttime Flu, Dimetapp Expectorant products, Dimetapp Nighttime Children's Cold and Congestion
<b>Product Use Classification</b>	Pharmaceutical product Analgesic, Antihistamine, Antitussive, Decongestant, Expectorant, Central Nervous System Agent
<b>Supplier</b>	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
<b>Emergency Telephone Number</b>	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**

None known

**Potential Health Effects**

**Eyes**

May cause irritation.

**Skin**

Not available

**Inhalation**

See ingestion

**Ingestion**

The most common effects may include allergy, nervousness, dizziness, sleeplessness, pain, cough, and liver damage.

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.

Not listed by OSHA, NTP or IARC.

**Potential Environmental Effects**

See Section 12.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Dextromethorphan HBr	125-69-9	0 - 3 mg/ml
Ibuprofen	15687-27-1	0 - 20 mg/ml
Brompheniramine Maleate	980-71-2	0 - 0.2 mg/ml
Acetaminophen	103-90-2	0 - 32 mg/ml
Pseudoephedrine HCl	345-78-8	0 - 9 mg/ml
Diphenhydramine HCl	147-24-0	0 - 1.25 mg/ml
Ethyl Alcohol	64-17-5	0-3.5%
Inactive Ingredients	Not applicable	Remainder
Phenylephrine HCl	61-76-7	0-5 mg/ml

### 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>	Slight fire hazard.
<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.
<b>Methods for Containment</b>	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**

Common Name	Exposure Guideline
Inactive Ingredients	250 mg/m <sup>3</sup>
Dextromethorphan HBr	630 mcg/m <sup>3</sup>
Ibuprofen	2000 mcg/m <sup>3</sup>
Brompheniramine Maleate	200 mcg/m <sup>3</sup>
Acetaminophen	2000 mcg/m <sup>3</sup>
Pseudoephedrine HCl	200 mcg/m <sup>3</sup>
Diphenhydramine HCl	500 mcg/m <sup>3</sup>
Ethyl Alcohol	1000 ppm
Phenylephrine HCl	40 mcg/m <sup>3</sup>

**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

<b>Appearance</b>	Pharmaceutical Liquid	<b>Physical State</b>	Liquid
<b>Color</b>	Various	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>pH</b>	various		
<b>Specific Gravity</b>	Not applicable	<b>Water Solubility</b>	Not available
<b>Solubility</b>	Not applicable	<b>Evaporation Rate</b>	Not applicable
<b>Partition Coefficient (n-octanol/water)</b>	Not available	<b>Vapor Pressure</b>	Not applicable

<b>Boiling Point</b>	Not available	<b>Autoignition Temperature</b>	Not applicable
<b>Flash Point</b>	Not applicable	<b>Method</b>	None
<b>Melting Point</b>	Not applicable		
<b>Flammability Limits in Air</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	
<b>Explosion Limits</b>	<b>Upper</b> Not applicable	<b>Lower</b> Not applicable	

## 10. STABILITY AND REACTIVITY

<b>Chemical Stability</b>	Stable at room temperature.
<b>Conditions to Avoid</b>	No data available
<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

#### **Dextromethorphan HBr**

<b>LD50 Oral</b>	350 mg/kg rats, 39-165 mg/kg mice
<b>Acute Dermal Irritation</b>	Not applicable
<b>Primary Eye Irritation</b>	Not applicable
<b>Sensitization</b>	Not applicable

#### **Ibuprofen**

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

#### **Brompheniramine Maleate**

<b>LD50 Oral</b>	318 mg/kg rats
<b>Acute Dermal Irritation</b>	Not applicable
<b>Primary Eye Irritation</b>	Not applicable
<b>Sensitization</b>	Not applicable

#### **Acetaminophen**

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

#### **Pseudoephedrine HCl**

<b>LD50 Oral</b>	371 mg/kg mice
<b>Acute Dermal Irritation</b>	No data available

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<b>Primary Eye Irritation</b>	No data available
<b>Sensitization</b>	No data available
<b>Diphenhydramine HCl</b>	
<b>LD50 Oral</b>	500 mg/kg rats, 164-200 mg/kg mice
<b>Acute Dermal Irritation</b>	Not applicable
<b>Primary Eye Irritation</b>	Not applicable
<b>Sensitization</b>	Not applicable
<b>Ethyl Alcohol</b>	
<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
<b>Phenylephrine HCl</b>	
<b>LD50 Oral</b>	350 mg/kg rats, 1400 mg/kg mice
<b>Acute Dermal Irritation</b>	Not irritating to rabbit skin.
<b>Primary Eye Irritation</b>	No data available
<b>Sensitization</b>	No data available
<b><u>Multiple Dose Toxicity</u></b>	
<b>Ethyl Alcohol</b>	
<b>No Toxicologic Effect</b>	Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.
<b>Dose/Species/Study Length:</b>	
<b><u>Maximum Tolerated Dose (MTD), Oral</u></b>	
<b>Acetaminophen</b>	
<b>Carcinogenicity</b>	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in male rats or mice. Equivocal evidence was seen in female rats. IARC Category 3.
<b>Genetic Toxicity</b>	Not mutagenic in AMES Test. Induced sister chromatid exchanges and chromosomal aberrations in cytogenetic tests using Chinese hamster ovary cells.
<b>Reproductive Toxicity</b>	Testicular atrophy and inhibition of spermatogenesis was seen in animal studies at high dose levels. Relevance to humans is not known.
<b>Developmental Toxicity</b>	See Reproductive Toxicity
<b>Diphenhydramine HCl</b>	
<b>Carcinogenicity</b>	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in mice. Equivocal evidence was seen in rats.
<b>Genetic Toxicity</b>	Non-mutagenic in <i>in vitro</i> studies.
<b>Reproductive Toxicity</b>	No data available
<b>Developmental Toxicity</b>	No evidence of teratogenic effects. were observed in pregnant rats at the highest doses administered where there were clear signs of maternal and fetal toxicity.
<b>Ethyl Alcohol</b>	
<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).
<b>Phenylephrine HCl</b>	

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<b>Carcinogenicity</b>	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.
<b>Genetic Toxicity</b>	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays.
<b>Reproductive Toxicity</b>	No data available
<b>Developmental Toxicity</b>	No data available
<b>Acetaminophen</b>	
<b>Target Organ(s) of Toxicity</b>	No data available
<b>Diphenhydramine HCl</b>	
<b>Target Organ(s) of Toxicity</b>	No data available
<b>Ethyl Alcohol</b>	
<b>Target Organ(s) of Toxicity</b>	No data available
<b>Phenylephrine HCl</b>	
<b>Target Organ(s) of Toxicity</b>	No data available

## 12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

### Chemical Fate Information

#### **Dextromethorphan HBr**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not inherently biodegradable.
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

#### **Ibuprofen**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not available
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

#### **Brompheniramine Maleate**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not available
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

#### **Acetaminophen**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not available
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

#### **Pseudoephedrine HCl**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Moderately biodegradable.
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

#### **Diphenhydramine HCl**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not available
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

#### **Phenylephrine HCl**

<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not available
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available

### Ecotoxicity

#### **Dextromethorphan HBr**

<b>Microorganisms</b>	EC50/3h >100 mg/l
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<b>Algae</b>	EC50/72h/algae = 2.4 mg/l, NOEC = 0.37 mg/l
<b>Daphnia</b>	EC50/48h/daphnia 14.5 mg/l, NOEC <5.8 mg/l
<b>Fish</b>	LC50/96h/rainbow trout = 4.9 mg/l
<b>Ibuprofen</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	Not available
<b>Brompheniramine Maleate</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	Not available
<b>Acetaminophen</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	Not available
<b>Pseudoephedrine HCl</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	LC50/96h/golden orfe = 460-1000 mg/l
<b>Diphenhydramine HCl</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	Not available
<b>Phenylephrine HCl</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	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.

<b>U.S. Department of Transport (DOT)</b>	Not regulated
<b>Canadian Transport of Dangerous Goods (TDG)</b>	Not regulated
<b>International Civil Aviation Organization (ICAO)</b>	Not regulated
<b>International Air Transport Association (IATA)</b>	Not regulated
<b>International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)</b>	Not regulated

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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	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
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>	Product Profiles
<b>Revision Summary</b>	Changes to Section 8

## Disclaimer:

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**End of MSDS**