# Robitussin Liquid Products

**Preparation Date** 19-Sep-2007  
**Revision Date** 09-Feb-2009  
**Revision Number** 7

## 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th><strong>Product Name</strong></th>
<th>Robitussin Liquid Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common Name</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Chemical Name</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
<td>Robitussin Cough Products; Robitussin Cough and Cold Products; Robitussin Congestion Products; Robitussin Cough, Cold and Flu Products; Robitussin Cough and Allergy Products; Robitussin Pediatric Products; Robitussin Nighttime Cough, Cold and Flu Products, Robitussin Nighttime Pediatric Cough and Cold Products, Robitussin Child Products, Extra Strength Products, Robitussin DM, Robitussin Nighttime Cough and Cold, Robitussin Cough and Cold CF, Robitussin DM</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Product Use</strong></th>
<th>Pharmaceutical product</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td>Analgesic, Antihistamine, Antitussive, Decongestant, Expectorant, Central Nervous System Agent</td>
</tr>
</tbody>
</table>

**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 is a research material that may affect body functions

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

### Potential Physical Hazards
None known

### Potential Health Effects

<table>
<thead>
<tr>
<th><strong>Eyes</strong></th>
<th>May cause irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Ingestion</strong></td>
<td>The most common effects may include allergy, gastrointestinal effects (ulcer, bleeding, perforation), drowsiness, nervousness, excitability, dizziness, sleeplessness, pain, and cough. May impair ability when driving a motor vehicle or operating machinery.</td>
</tr>
</tbody>
</table>

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

Please see Patient Package Insert for further information.

<table>
<thead>
<tr>
<th><strong>Therapeutic Target Organ(s)</strong></th>
<th>Nervous system, respiratory system.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential Environmental Effects</strong></td>
<td>See Section 12</td>
</tr>
</tbody>
</table>
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>103-90-2</td>
<td>0 - 32 mg/ml</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>113-92-8</td>
<td>0 - 0.4 mg/ml</td>
</tr>
<tr>
<td>Dextromethorphan HBr</td>
<td>125-69-9</td>
<td>0 - 3 mg/ml</td>
</tr>
<tr>
<td>Diphenhydramine HCl</td>
<td>147-24-0</td>
<td>0 - 1.25 mg/ml</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>61-76-7</td>
<td>0 - 1 mg/ml</td>
</tr>
<tr>
<td>Guaifenesin</td>
<td>93-14-1</td>
<td>0 - 40 mg/ml</td>
</tr>
<tr>
<td>Brompheniramine Maleate</td>
<td>980-71-2</td>
<td>0 - 0.4 mg/ml</td>
</tr>
<tr>
<td>Pseudoephedrine HCl</td>
<td>345-78-8</td>
<td>0 - 6 mg/ml</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Eye Contact: In case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact: Wash off immediately with soap and plenty of water.

Inhalation: Artificial respiration and/or oxygen may be necessary.

Ingestion: Immediate medical attention is not required.

5. FIRE-FIGHTING MEASURES

- Flammable Properties: No data available.
- Extinguishing Media:
  - Suitable Extinguishing Media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
  - Unsuitable Extinguishing Media: Do not use a solid water stream as it may scatter and spread fire
- Fire Fighting: Evacuate area and fight fire from a safe distance
- Hazardous Combustion Products: Hazardous Combustion Products
- Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

- Personal Precautions: Safety glasses or goggles when splash potential exists
- Environmental Precautions: 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
7. HANDLING AND STORAGE

Handling
Handle in accordance with good industrial hygiene and safety practice

Storage
Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Exposure Guideline
Acetaminophen 2000 mcg/m³
Chlorpheniramine Maleate 10 mcg/m³
Dextromethorphan HBr 630 mcg/m³
Diphenhydramine HCl 500 mcg/m³
Phenylephrine HCl 40 mcg/m³
Guaiifenesin 3000 mcg/m³
Brompheniramine Maleate 200 mcg/m³
Pseudoephedrine HCl 200 mcg/m³

Engineering Controls
Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for 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

Other
Limit access to only personnel trained in the safe handling of this material

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Pharmaceutical Liquid

Color
Various

Odor Threshold
Not available

pH
various

Specific Gravity
Not applicable

Solubility
Not applicable

Partition Coefficient (n-octanol/water)
Not available

Boiling Point
Not available

Flash Point
Not available

Melting Point
Not applicable

Flammability Limits in Air
Upper Not applicable

Explosion Limits
Upper Not applicable

Physical State
Liquid

Odor
Not available

Water Solubility
Not applicable

Evaporation Rate
Not applicable

Vapor Pressure
Not applicable

Autoignition Temperature Method
None

Upper
Lower

Not applicable

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

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

Brompheniramine Maleate
LD50 Oral 318 mg/kg rats
Acute Dermal Irritation Not applicable
Primary Eye Irritation Not applicable
Sensitization Not applicable

Chlorpheniramine Maleate
LD50 Oral 118-680 mg/kg rats, 121 mg/kg mice
Acute Dermal Irritation No data available
Primary Eye Irritation No data available
Sensitization No data available

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

Diphenhydramine HCl
LD50 Oral 500 mg/kg rats, 164-200 mg/kg mice
Acute Dermal Irritation Not applicable
Primary Eye Irritation Not applicable
Sensitization Not applicable

Guaifenesin
LD50 Oral 1510 mg/kg rats
Acute Dermal Irritation Not applicable
Primary Eye Irritation Not applicable
<table>
<thead>
<tr>
<th>Substance</th>
<th>Sensitization</th>
<th>LD50 Oral</th>
<th>Acute Dermal Irritation</th>
<th>Primary Eye Irritation</th>
<th>Sensitization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenylephrine HCl</td>
<td>Not applicable</td>
<td>350 mg/kg rats, 1400 mg/kg mice</td>
<td>Not irritating to rabbit skin.</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Pseudoephedrine HCl</td>
<td>371 mg/kg mice</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>This compound was well tolerated in rats and mice in repeat-dose toxicity studies for 13 weeks. There was a reduction of body weight gain and reduced survival at higher doses.</td>
<td>LD50 Oral</td>
<td>No Toxicologic Effect</td>
<td>Dose/Species/Study Length: See Reproductive Toxicity</td>
<td></td>
</tr>
</tbody>
</table>

### Maximum Tolerated Dose (MTD), Oral

<table>
<thead>
<tr>
<th>Substance</th>
<th>Carcinogenicity</th>
<th>Genetic Toxicity</th>
<th>Reproductive Toxicity</th>
<th>Developmental Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>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.</td>
<td>Not mutagenic in AMES Test. Induced sister chromatid exchanges and chromosomal aberrations in cytogenetic tests using Chinese hamster ovary cells.</td>
<td>Animal studies to evaluate effects on fertility have not been conducted.</td>
<td>See Reproductive Toxicity</td>
</tr>
<tr>
<td>Chlorpheniramine Maleate</td>
<td>Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in male or female rats or mice.</td>
<td>No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays.</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Diphenhydramine HCl</td>
<td>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.</td>
<td>Non-mutagenic in in vitro studies.</td>
<td>No data available</td>
<td>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.</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in male or female rats or mice.</td>
<td>No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays.</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Acetaminophen
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Dextromethorphan HBr

- Mobility: Not available
- Biodegradability: Not inherently biodegradable.
- Stability in Water: Not available
- Bioaccumulation: Not available

Ecotoxicity

Dextromethorphan HBr

- Microorganisms: EC50/3h >100 mg/l
- Algae: EC50/72h/algae = 2.4 mg/l, NOEC = 0.37 mg/l
- Daphnia: EC50/daphnia > 14.5 mg/l mg/l, NOEC = 14.5 mg/l mg/l
- Fish: LC50/96h/rainbow trout = 4.9 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
- 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: 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
This product does not contain any Proposition 65 chemicals

Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
Not Determined
### 16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>Prepared By</th>
<th>Wyeth Department of Environment, Health &amp; Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format</td>
<td>This MSDS was prepared in accordance with ANSI Z400.1-2004.</td>
</tr>
<tr>
<td>List of References</td>
<td>Product Profiles</td>
</tr>
<tr>
<td>Revision Summary</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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