Material Safety Data Sheet
ANSI Format

Robitussin Liquid Products

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

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Robitussin Liquid Products
Common Name	Not applicable
Chemical Name	Not applicable
Synonyms	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
Product Use	Pharmaceutical product
Classification	Analgesic, Antihistamine, Antitussive, Decongestant, Expectorant, Central Nervous System 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 is a research material that may affect body functions

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	Not available
Ingestion	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. 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
Acetaminophen	103-90-2	0 - 32 mg/ml
Chlorpheniramine Maleate	113-92-8	0 - 0.4 mg/ml
Dextromethorphan HBr	125-69-9	0 - 3 mg/ml
Diphenhydramine HCl	147-24-0	0 - 1.25 mg/ml
Phenylephrine HCl	61-76-7	0 - 1 mg/ml
Guaifenesin	93-14-1	0 - 40 mg/ml
Brompheniramine Maleate	980-71-2	0 - 0.4 mg/ml
Pseudoephedrine HCl	345-78-8	0 - 6 mg/ml
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact In case of contact with eyes, rinse immediately with plenty of water for 15 mintues 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/m^3
Chlorpheniramine Maleate	10 mcg/m^3
Dextromethorphan HBr	630 mcg/m^3
Diphenhydramine HCl	500 mcg/m^3
Phenylephrine HCl	40 mcg/m^3
Guaifenesin	3000 mcg/m^3
Brompheniramine Maleate	200 mcg/m^3
Pseudoephedrine HCl	200 mcg/m^3

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	**Physical State**	Liquid
Color	Various	**Odor**	Not available
Odor Threshold	Not available		
pH	various		
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 applicable
Flash Point	Not available	**Method**	None
Melting Point	Not applicable		
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

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

Sensitization	Not applicable

Phenylephrine HCl

LD50 Oral	350 mg/kg rats, 1400 mg/kg mice
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	No data available
Sensitization	No data available

Pseudoephedrine HCl

LD50 Oral	371 mg/kg mice
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Multiple Dose Toxicity Not available

Chlorpheniramine Maleate

No Toxicologic Effect Dose/Species/Study Length:	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.

Maximum Tolerated Dose (MTD), Oral

Acetaminophen

Carcinogenicity	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.
Genetic Toxicity	Not mutagenic in AMES Test. Induced sister chromatid exchanges and chromosomal aberrations in cytogenetic tests using Chinese hamster ovary cells.
Reproductive Toxicity	Testicular atrophy and inhibition of spermatogenesis was seen in animal studies at high dose levels. Relevance to humans is not known.
Developmental Toxicity	See Reproductive Toxicity

Chlorpheniramine Maleate

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	Animal studies to evaluate effects on fertility have not been conducted.
Developmental Toxicity	No teratogenic effects were observed in mice.

Diphenhydramine HCl

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in mice. Equivoval evidence was seen in rats.
Genetic Toxicity	Non-mutagenic in *in vitro* studies.
Reproductive Toxicity	No data available
Developmental Toxicity	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.

Phenylephrine HCl

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Acetaminophen

Target Organ(s) of Toxicity No data available

Chlorpheniramine Maleate
Target Organ(s) of Toxicity No data available

Diphenhydramine HCl
Target Organ(s) of Toxicity No data available

Phenylephrine HCl
Target Organ(s) of Toxicity No data available

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

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	Product Profiles
Revision Summary	Not applicable

Disclaimer:

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