



Robitussin - DAC

Preparation Date 19-Sep-2007

Revision Date 19-Sep-2007

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Robitussin - DAC
Common Name Not applicable
Chemical Name Not applicable
Synonyms Robitussin- DAC
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 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 Slight fire hazard.

Potential Health Effects

Eyes May cause irritation.
Skin Not available
Inhalation Not available
Ingestion The most common effects may include allergy, drowsiness, nervousness, excitability, dizziness, sleeplessness, and constipation. 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 There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Pseudoephedrine HCl	345-78-8	<1%
Guaifenesin	93-14-1	>1%
Codeine Phosphate	52-28-8	<1%
Inactive Ingredients	Not applicable	Remainder
Ethyl Alcohol	64-17-5	>1%

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	Slight fire hazard.
Extinguishing Media	
Suitable Extinguishing Media	Use alcohol-resistant 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

Common Name	Exposure Guideline
Guaifenesin	3000 mcg/m ³
Codeine Phosphate	200 mcg/m ³
Pseudoephedrine HCl	200 mcg/m ³
Ethyl Alcohol	1000 ppm
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 Liquid	Physical State	Liquid
Color	Red	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not available
Boiling Point	Not available	Autoignition Temperature Method	Not available
Flash Point	>110°C		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

Guaifenesin

LD50 Oral	1510 mg/kg rats
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Codeine Phosphate

LD50 Oral	427 mg/kg rats, 250 mg/kg mice
Acute Dermal Irritation	No data available
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

Ethyl Alcohol

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

Multiple Dose Toxicity

Guaifenesin

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

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

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

Maximum Tolerated Dose (MTD), Oral**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.

Codeine Phosphate

Carcinogenicity Long-term studies in rats and mice revealed no evidence of carcinogenicity.
Genetic Toxicity No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity At a maternally toxic dose of 120 mg/kg/day, embryo resorptions at the time of implantation were reported. In pregnant mice, a single dose of 100 mg/kg resulted in delayed ossification of offspring.
Developmental Toxicity No teratogenic effects were observed in rats or rabbits.

Pseudoephedrine HCl

Carcinogenicity No data available
Genetic Toxicity No data available
Reproductive Toxicity No data available
Developmental Toxicity No data available

Ethyl Alcohol

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

Guaifenesin

Target Organ(s) of Toxicity No data available

Codeine Phosphate

Target Organ(s) of Toxicity No data available

Pseudoephedrine HCl

Target Organ(s) of Toxicity No data available

Ethyl Alcohol

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

Pseudoephedrine HCl

Mobility	Not available
Biodegradability	Moderately biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available

Ethanol

Mobility	May adsorb on sludge or particles in natural waters.
Biodegradability	Not available
Stability in Water	Hydrolyses in water.
Bioaccumulation	Bioaccumulative potential.

Ecotoxicity Not available

Pseudoephedrine HCl

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	LC50/96h/golden orfe = 460-1000 mg/l

Ethanol

Microorganisms	EC50 > Aqueous solubility limit
Algae	EC50/72h/algae = 0.063 mg/l, NOEC = 0.015 mg/l
Daphnia	EC50/48h/daphnia > Aqueous solubility limit, NOEC = Aqueous solubility limit
Fish	LC50/96h/fathead minnow > Aqueous solubility limit, NOEC > Aqueous solubility limit

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	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 contains the following Proposition 65 chemicals:

Common Name	CAS-No	Type
Codeine Phosphate	52-28-8	Developmental

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	ToxNet, Toxicology Data Network, US National Library of Medicine
Revision Summary	Updated for Canadian Products, Changes to Section 2 and 11

Disclaimer:

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