



Material Safety Data Sheet

ANSI Format

Advil Liquid Products

Preparation Date 19-Sep-2007

Revision Date 19-Sep-2007

Revision Number 3

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Advil Liquid Products
Common Name	Not applicable
Chemical Name	Not applicable
Synonyms	Children's Advil Suspension, Children's Advil Cold Suspension, Children's Advil Allergy Sinus, Advil Infant Drops, Ibuprofen
Product Use	Pharmaceutical product
Classification	Analgesic, Antipyretic
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
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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
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Potential Physical Hazards	None known
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Potential Health Effects

Eyes	May cause eye irritation.
Skin	May cause skin irritation.
Inhalation	May cause mucous membrane and upper respiratory tract irritation.
Ingestion	The most common effects may include severe allergic reaction (hives, facial swelling, wheezing, shock, skin reddening, rash, blisters), stomach bleeding (faintness, bloody vomit, bloody or black stools), nervousness, dizziness, and sleeplessness.

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, Gastrointestinal system.
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Not listed by OSHA, NTP or IARC.

Potential Environmental Effects	There is no known ecological information for this product.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Ibuprofen	15687-27-1	20 - 40 mg/ml
Chlorpheniramine Maleate	113-92-8	0 - 0.2 mg/ml
Pseudoephedrine HCl	345-78-8	0 - 3 mg/ml
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

Common Name	Exposure Guideline
Ibuprofen	2000 mcg/m ³
Chlorpheniramine Maleate	10 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 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	Various	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 applicable
Flash Point	Not applicable	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**Ibuprofen**

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

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

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**Ibuprofen**

No Toxicologic Effect	Not available
Dose/Species/Study Length:	

Chlorpheniramine Maleate

No Toxicologic Effect	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.
Dose/Species/Study Length:	

Pseudoephedrine HCl

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

Maximum Tolerated Dose (MTD), Oral**Ibuprofen**

Carcinogenicity	Carcinogenic studies in mice and rats were negative.
Genetic Toxicity	Non-mutagenic in <i>in vivo</i> studies.
Reproductive Toxicity	Reproduction studies in rats and mice did not reveal any evidence of impaired fertility or embryotoxicity.
Developmental Toxicity	Reproduction studies in rats and mice did not reveal any teratogenic effects.
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 <i>in vitro</i> and <i>in vivo</i> assays.
Reproductive Toxicity	Animal studies to evaluate effects on fertility have not been conducted.
Developmental Toxicity	No teratogenic effects were observed in mice.
Pseudoephedrine HCl	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Ibuprofen	
Target Organ(s) of Toxicity	No data available
Chlorpheniramine Maleate	
Target Organ(s) of Toxicity	No data available
Pseudoephedrine 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	Not available
Ecotoxicity	Not available

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	No
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	ToxNet, Toxicology Data Network, US National Library of Medicine
Revision Summary	Changes to Section 11

Disclaimer:

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End of MSDS