



# 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

### 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 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.

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
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**

<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>	Presumed to be a combustible particulate solid.
<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
<b>Methods for Cleaning up</b>	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

## 7. HANDLING AND STORAGE

<b>Handling</b>	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.
<b>Storage</b>	No special safety precautions required. Keep container tightly closed.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Common Name</b>	<b>Exposure Guideline</b>
Ibuprofen	2000 mcg/m <sup>3</sup>
Chlorpheniramine Maleate	10 mcg/m <sup>3</sup>
Pseudoephedrine HCl	200 mcg/m <sup>3</sup>
<b>Engineering Controls</b>	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.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Provide eye protection based on risk assessment.
<b>Skin Protection</b>	Wear nitrile or latex gloves. Wear protective garment.
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment.
<b>General Hygiene Considerations</b>	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
<b>Other</b>	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>	Not available		
<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****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

**Chlorpheniramine Maleate**

<b>LD50 Oral</b>	118-680 mg/kg rats, 121 mg/kg mice
<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
<b>Primary Eye Irritation</b>	No data available
<b>Sensitization</b>	No data available

**Multiple Dose Toxicity****Ibuprofen**

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	Not available
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**Chlorpheniramine Maleate**

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	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.
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**Pseudoephedrine HCl**

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	No data available
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**Maximum Tolerated Dose (MTD), Oral****Ibuprofen**

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

<u>Chemical Fate Information</u>	Not available
<u>Ecotoxicity</u>	Not available

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal Method</b>	Dispose of in accordance with local and national regulations.
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## 14. TRANSPORT INFORMATION

<b>Transport Information</b>	This material is not classified as hazardous for transport.
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<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
<b>Transport of Dangerous Goods by Rail (RID)</b>	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.

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**16. OTHER INFORMATION**

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**Prepared By**

Wyeth Department of Environment, Health &amp; 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**