Material Safety Data Sheet
ANSI Format

Advil Solid Products

Preparation Date 06-Dec-2006 **Revision Date** 26-Sep-2007 **Revision Number** 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Advil Solid Products
Common Name	Not applicable
Chemical Name	Not applicable
Synonyms	Advil Tablets, Advil Caplets, Advil Gel Caplets, Advil Liqui-Gels, Advil Migraine, Advil Cold & Sinus, Advil Allergy Sinus, Advil Flu & Body Ache, Advil PM, Advil Multi-Symptom Cold, Junior Strength Advil Coated Tablets, Junior Strength Advil Chewables, Children's Advil Chewables, Ibuprofen, Advil Maximum Strength
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 Tablet , Capsule **Physical State** Solid **Odor** Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

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	50 - 400 mg/tablet
Chlorpheniramine Maleate	113-92-8	0 - 2 mg/tablet
Pseudoephedrine HCl	345-78-8	0 - 30 mg/tablet
Diphenhydramine Citrate	88637-37-0	0 - 38 mg/tablet
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

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 Tablet , Capsule	**Physical State**	Solid
Color	Various	**Odor**	Not available
Odor Threshold	Not available		
pH	Not applicable		
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 applicable	**Autoignition Temperature**	Not applicable
Flash Point	Not applicable25 - 29°C -	**Method**	None
Melting Point	Not available		
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

Diphenhydramine Citrate

LD50 Oral	500 mg/kg rats
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Ibuprofen

No Toxicologic Effect Dose/Species/Study Length:	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.

Pseudoephedrine HCl

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

Diphenhydramine Citrate

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

Maximum Tolerated Dose (MTD), Oral

Ibuprofen

Carcinogenicity	Carcinogenic studies in mice and rats were negative.
Genetic Toxicity	Non-mutagenic in *in vivo* 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 *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.

Pseudoephedrine HCl

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

Diphenhydramine Citrate

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was a slight increased incidence of uncommon brain neoplasm in male rats and a slight increased incidence of pituitary gland adenomas and areolar bronchial neoplasms in female rats. Carcinogenic studies in mice and rats were negative.
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	Developmental toxicity studies in rats and rabbits have revealed no evidence of harm to fetus. There was an increased incidence of cleft palate in mice, but only at levels that were toxic to the mother and the fetus.

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

Diphenhydramine Citrate

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.

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	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 composition and Addition to synonyms.

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