



Advil Spray Actief

Preparation Date 29-Aug-2007

Revision Date 21-Aug-2007

Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Advil Spray Actief
Common Name Not available
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 or gel **Physical State** Liquid **Odor** Not available

Potential Physical Hazards Flammable liquid.

Potential Health Effects

Eyes
Skin

May cause eye irritation
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.

Inhalation
Ingestion

May cause mucous membrane and upper respiratory tract irritation.
May be harmful if swallowed.

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) Skin, Nervous system, Gastrointestinal system

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Ibuprofen	15687-27-1	5%
Levomenthol	89-78-1	3%
Isopropanol	67-63-0	40%
Sodium Hydroxide	1310-73-2	0.96%
Water	7732-18-5	51.04%

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	Flammable liquid. Vapors may cause flash fire or explosion..
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. Take precautionary measures against static discharges. Keep away from open flames, hot surfaces and sources of ignition. When processing, use electrically classified equipment.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	Exposure Guideline
Ibuprofen	2000 mcg/m ³
Levomethol	None assigned
Isopropanol	200 ppm (ACGIH)
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 or gel	Physical State	Liquid
Color	Not available	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not available	Water Solubility	Not available
Solubility	Not available	Evaporation Rate	Not available
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	Keep away from heat and sources of ignition.
Materials to Avoid	May be incompatible with acids, bases and oxidizers.
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

Levomenthol

LD50 Oral	3180 mg/kg rat
Acute Dermal Irritation	No data available
Primary Eye Irritation	Severe eye irritation, 250 mcg rabbit
Sensitization	No data available

Isopropanol

LD50 Oral	4,700 - 5,800 mg/kg rat
Acute Dermal Irritation	13,000 mg/kg rabbit
Primary Eye Irritation	No data available
Sensitization	No data available

Multiple Dose Toxicity

Ibuprofen

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

Levomenthol

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

Isopropanol

No Toxicologic Effect Dose/Species/Study Length:	In animals, effects have been reported on the liver. Observations have included lethargy, kidney effects and/or tumors have been observed in male rats. These effects are believed to be species specific and unlikely to occur in humans.
---	--

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.

Levomenthol

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

Isopropanol

Carcinogenicity	Animal testing did not show any carcinogenic effects.
Genetic Toxicity	Negative in a battery of genotoxicity tests.
Reproductive Toxicity	Did not show reproductive toxicity effects in animal experiments.
Developmental Toxicity	In animal studies, found to be toxic to the fetus at maternally toxic doses.

Ibuprofen

Target Organ(s) of Toxicity	No data available
------------------------------------	-------------------

Levomenthol

Target Organ(s) of Toxicity	No data available
------------------------------------	-------------------

Isopropanol

Target Organ(s) of Toxicity	No data available
------------------------------------	-------------------

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Ibuprofen

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Levomenthol

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Isopropanol

Mobility	High potential for mobility in soil.
Biodegradability	Readily biodegradable (95% after 21 days)
Stability in Water	Not available
Bioaccumulation	Bioaccumulation is unlikely.

Ecotoxicity

Ibuprofen

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

Levomenthol

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

Isopropanol

Microorganisms	EC50/bacteria > 1000 mg/l
Algae	EC50/72h/algae > 1000 mg/l
Daphnia	EC50/48h/daphnia = 7550 - 13299 mg/l,
Fish	LC50/96h/fathead minnow = 8680 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	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 Goldman to VonKaenel email Aug 3, 2007
Revision Summary Updated for Canadian Products

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS