



**Anacin Products**

Preparation Date 20-Aug-2007

Revision Date 31-Mar-2008

Revision Number 4

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name** Anacin Products  
**Common Name** Not available  
**Chemical Name** Not applicable  
**Synonyms** Anacin Tablets, Anacin Aspirin Free, Anacin Extra Strength  
**Product Use** Pharmaceutical product  
**Classification** Antipyretic, Analgesic

**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 , Caplet  
**Physical State** Solid  
**Odor** Not available

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

**Potential Health Effects**

**Eyes** Not available  
**Skin** Not available  
**Inhalation** Not available  
**Ingestion** The most common effects may include Reye's Syndrome, severe allergic reaction (hives, facial swelling, asthma (wheezing), shock), ringing in the ears, or loss of hearing.

May affect the unborn child. Excreted in breast milk.

Please see Patient Package Insert for further information.

**Therapeutic Target Organ(s)** Systemic.

Not listed by OSHA, NTP or IARC.

**Potential Environmental Effects** See Section 12.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Acetaminophen	103-90-2	0-500 mg/tablet
Acetylsalicylate Acid	50-78-2	0-500 mg/tablet
Caffeine	58-08-2	0-32 mg/tablet
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>
Inactive Ingredients	250 mg/m <sup>3</sup>
Acetaminophen	2000 mcg/m <sup>3</sup>
Acetylsalicylate Acid	750 mcg/m <sup>3</sup>
Caffeine	500 mcg/m <sup>3</sup>

**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

<b>Appearance</b>	Pharmaceutical Tablet , Caplet	<b>Physical State</b>	Solid
<b>Color</b>	Various	<b>Odor</b>	Not available
<b>Odor Threshold</b>	Not available		
<b>pH</b>	Not applicable		
<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 applicable	<b>Autoignition Temperature Method</b>	Not applicable
<b>Flash Point</b>	Not applicable		None
<b>Melting Point</b>	Not available		
<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

#### Acetaminophen

<b>LD50 Oral</b>	2404 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

#### Acetylsalicylate Acid

<b>LD50 Oral</b>	1460 mg/kg rats, 1100 mg/kg mice, 1010 mg/kg rabbits
<b>Acute Dermal Irritation</b>	7940 mg/kg rabbits, slightly irritating to rabbit skin.
<b>Primary Eye Irritation</b>	Irritating to rabbit eyes.
<b>Sensitization</b>	Not a dermal sensitizer in guinea pigs.

#### Caffeine

<b>LD50 Oral</b>	192 mg/kg rats, 125 mg/kg mice
<b>Acute Dermal Irritation</b>	> 2000 mg/kg rats
<b>Primary Eye Irritation</b>	Not irritating to rabbit eyes.
<b>Sensitization</b>	No data available

### Multiple Dose Toxicity

#### Acetylsalicylate Acid

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	See Carcinogenicity
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#### Caffeine

<b>No Toxicologic Effect Dose/Species/Study Length:</b>	See Carcinogenicity
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### Maximum Tolerated Dose (MTD), Oral

#### Acetaminophen

<b>Carcinogenicity</b>	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in male rats or mice. Equivocal evidence was seen in female rats. IARC Category 3.
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<b>Genetic Toxicity</b>	Not mutagenic in AMES Test. Induced sister chromatid exchanges and chromosomal aberrations in cytogenetic tests using Chinese hamster ovary cells.
<b>Reproductive Toxicity</b>	Testicular atrophy and inhibition of spermatogenesis was seen in animal studies at high dose levels. Relevance to humans is not known.
<b>Developmental Toxicity</b>	See Reproductive Toxicity
<b>Acetylsalicylate Acid</b>	
<b>Carcinogenicity</b>	Long-term studies in rats revealed no evidence of carcinogenicity.
<b>Genetic Toxicity</b>	AMES Test :Negative- Nonmutagenic Positive in the <i>in vivo</i> chromosome aberration assay in cultured fibroblasts.
<b>Reproductive Toxicity</b>	See Developmental Toxicity.
<b>Developmental Toxicity</b>	Fetotoxin and a teratogen in rats, mice, dogs, cats and monkeys at high doses.
<b>Caffeine</b>	
<b>Carcinogenicity</b>	In a 2-year study in rats and mice, no evidence of carcinogenic potential was observed.
<b>Genetic Toxicity</b>	Evidence of Genotoxicity was observed in a battery of studies.
<b>Reproductive Toxicity</b>	Studies in monkeys have resulted in reduced fetal weight, stillbirths, and miscarriages.
<b>Developmental Toxicity</b>	Teratogenic effects were reported in both rats and mice at high doses (> 40 mg/kg/day). Digital defects, cleft palate, extra embryonic structures, and urogenital and musculoskeletal abnormalities were induced. Other findings in animal studies include inhibition of neurogenesis in the mouse embryo; reduced cerebral weight and cardiovascular, lens and thymic changes in rats.
<b>Acetaminophen</b>	
<b>Target Organ(s) of Toxicity</b>	No data available
<b>Acetylsalicylate Acid</b>	
<b>Target Organ(s) of Toxicity</b>	No data available
<b>Caffeine</b>	
<b>Target Organ(s) of Toxicity</b>	No data available

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## 12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

<b><u>Chemical Fate Information</u></b>	Not available
<b>Acetaminophen</b>	
<b>Mobility</b>	Not available
<b>Biodegradability</b>	Not available
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Not available
<b>Acetylsalicylate Acid</b>	
<b>Mobility</b>	Not available
<b>Biodegradability</b>	Readily biodegradable.
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Bioaccumulation is unlikely.
<b>Caffeine</b>	
<b>Mobility</b>	Not available
<b>Biodegradability</b>	Readily biodegradable.
<b>Stability in Water</b>	Not available
<b>Bioaccumulation</b>	Bioaccumulation is unlikely.
<b><u>Ecotoxicity</u></b>	Not available
<b>Acetaminophen</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	Not available
<b>Fish</b>	Not available
<b>Acetylsalicylate Acid</b>	
<b>Microorganisms</b>	Not available
<b>Algae</b>	Not available
<b>Daphnia</b>	EC50/48h/daphnia = 330 mg/l
<b>Fish</b>	Not available
<b>Caffeine</b>	
<b>Microorganisms</b>	EC50/17h/bacteria = 3490 mg/l
<b>Algae</b>	EC50/72h/green algae > 100 mg/l
<b>Daphnia</b>	EC50/48h/daphnia = 182 mg/l
<b>Fish</b>	LC50/96h/golden orfe = 87 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 contains the following Proposition 65 chemicals:

Common Name	CAS-No	Type
Acetylsalicylate Acid	50-78-2	Developmental Female Reproductive

#### 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**

<b>Prepared By</b>	Wyeth Department of Environment, Health & Safety
<b>Format</b>	This MSDS was prepared in accordance with ANSI Z400.1-2004.
<b>List of References</b>	Product Profiles
<b>Revision Summary</b>	Changes to Section 8

## Disclaimer:

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**End of MSDS**