



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-816-8129  
8 a.m. to 5 p.m. EST Mon. - Fri.

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## ACETAMINOPHEN

Catalog Number: 1003009

Revision Date:

August 17, 2005

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Acetaminophen

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

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**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

**Adverse Effects:** Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** Acute overdose effects include gastrointestinal distress and increased sweating. Effects of liver damage (which may be delayed by two or more days) include pain, tenderness, or swelling of the upper abdomen; mental changes; convulsions; respiratory depression; coma; cerebral edema; bleeding problems; hypoglycemia; metabolic acidosis; cardiac arrhythmias; and cardiovascular collapse. Kidney failure may also occur.

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material, active alcoholism, liver disease, viral hepatitis, and impaired kidney function.

**Cross Sensitivity:** Rarely, persons sensitive to aspirin may be sensitive to this material as well.

**Target Organs:** Liver.

**For additional information on toxicity, see Section 11.**

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Acetaminophen

**Formula:** C<sub>8</sub>H<sub>9</sub>NO<sub>2</sub>

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**Synonym:** Paracetamol

**Chemical Name:** Acetamide, N-(4-hydroxyphenyl)-

**CAS:** 103-90-2

**RTECS Number:** AE4200000

**Chemical Family:** Aniline derivative

**Therapeutic Category:** Analgesic; antipyretic

**Composition:** Pure Material

## SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause irritation. Flush with copious quantities of water.

**Skin:** May cause irritation. Flush with copious quantities of water.

**Ingestion:** May cause irritation and toxicity. Flush out mouth with water. This material is readily absorbed from the gastrointestinal tract. The duration of action is 3 to 4 hours.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

### Note to Physicians

**Overdose Treatment:** Treatment for acetaminophen overdose should be symptomatic and supportive and may include the following:

1. Empty the stomach via induced vomiting or gastric lavage. Do not administer activated charcoal as it may interfere with absorption of acetylcysteine and decrease its efficacy.
2. Administer acetylcysteine (an antidote used to protect against acetaminophen-induced hepatotoxicity) as soon as possible following an overdose.
3. Determine plasma acetaminophen concentration at least 4 hours following ingestion of the overdose. Determinations performed prior to this time are not reliable.
4. Instituting hemodialysis or hemoperfusion to remove acetaminophen from the circulation may be beneficial if acetylcysteine administration cannot be instituted within 24 hours following ingestion of massive overdose.
5. Perform liver function tests every 24 hours for at least 96 hours post-ingestion (if the plasma acetaminophen concentration indicates potential hepatotoxicity).
6. Monitor renal and cardiac function and administer appropriate therapy as required.
7. Institute supportive treatment, including maintaining fluid and electrolyte balance, correcting hypoglycemia, and administering vitamin K1, fresh frozen plasma, or clotting factor concentrate if needed. [USP DI 2005]

## SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately-labelled container for disposal. Wash spill site.

## SECTION 7 - HANDLING AND STORAGE

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**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

### SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety glasses or goggles

**Protective Clothing:** Protect exposed skin.

**Exposure Limits:** n/f

### SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

**Appearance and Odor:** White crystalline powder; odorless.

**Odor Threshold:** n/f

**pH:** 5.3 to 6.5 (saturated solution)

**Melting Range:** 169 - 171° C

**Boiling Point:** > 500° C

**Flash Point:** n/f

**Autoignition Temperature:** >= 180° C

**Evaporation Rate:** n/f

**Upper Flammability Limit:** n/f

**Lower Flammability Limit:** n/f

**Vapor Pressure:** n/f

**Vapor Density:** n/f

**Specific Gravity:** 1.293

**Solubility in Water:** Soluble in hot water

**Fat Solubility:** n/f

**Other Solubility:** Freely soluble in alcohol and in 1 N sodium hydroxide.

**Partition Coefficient: n-octanol/water:** 0.51

**Percent Volatile:** n/f

**Reactivity in Water:** n/f

**Explosive Properties:** n/f

**Oxidizing Properties:** n/f

**Formula:** C<sub>8</sub>H<sub>9</sub>NO<sub>2</sub>

**Molecular Weight:** 151.18

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## SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Avoid exposure to light and heat.

**Incompatibilities:** n/f

**Decomposition Products:** When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

## SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: 1944 mg/kg

**Oral Mouse:** LD50: 338 mg/kg

**Other Toxicity Data:** Guinea pig: LD50: 2620 mg/kg

**Irritancy Data:** n/f

**Corrosivity:** n/f

**Sensitization Data:** n/f

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** No      **OSHA:** No

**Other Carcinogenicity Data:** This material is not classifiable as to its carcinogenicity in humans.  
NTP Carcinogenesis Studies (feed): Equivocal Evidence (female rat); No Evidence (male rat; mouse)

**Mutagenicity Data:** n/f

**Reproductive and Developmental Effects:** Chronic toxicity studies in animals have shown that high doses of acetaminophen cause testicular atrophy and inhibition of spermatogenesis; the relevance of this finding to therapeutic use in humans is not known. Pregnancy problems in humans have not been documented.

## SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** Fathead minnow: LC50: 814 mg/L/96 hr (flow-through)  
Water flea: LC50: 55 mg/L/24 hr  
Daphnia magna: LC50: 9.2 mg/L/48 hr

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

## SECTION 14 - TRANSPORT INFORMATION

**Shipping Name:** n/f

**Class:** n/f

**UN Number:** n/f

**Packing Group:** n/f

**Additional Transport Information:** n/f

## SECTION 15 - REGULATORY INFORMATION

**U.S. Regulatory Information:** EINECS # 203-157-5  
Hazard code: Xn  
Risk phrases: R22  
Safety phrases: S22/24/25, S36/37/39

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International Regulatory Information: n/f

<b>SECTION 16 - OTHER INFORMATION</b>
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Previous Revision Date: 07-Jan-02