

1. Identification

Product identifier	Acetaminophen	
Other means of identification		
Catalog number	1003009	
Chemical name	Acetamide, N-(4-hydroxyphenyl)-, 4'-hydroxyacetanilide	
Synonym(s)	Paracetamol	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Note	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	
Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Warning	
Hazard statement	Harmful if swallowed.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Do not eat, drink or smoke when using this product.	
Response	Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell.	
Storage	Not available.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Acetaminophen	Paracetamol	103-90-2	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
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Skin contact	Immediately flush skin with plenty of water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops or persists.
Ingestion	Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Treatment for acetaminophen overdose should be symptomatic and supportive and may include the following: 1. Activated charcoal may be used to reduce gastrointestinal absorption, if it can be given within 1 hour of the overdose and if more than 150 mg/kg of paracetamol has been ingested. 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; Martindale 2009]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
5. Fire-fighting measures	
Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.
6. Accidental release measures	
Personal precautions, protective equipment and emergency procedures	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.
7. Handling and storage	
Precautions for safe handling	Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Acetaminophen (CAS 103-90-2)	TWA	5 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White crystalline powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless.

Odor threshold

Not available.

pH

5.1 - 6.5 (Saturated aqueous solution)

Melting point/freezing point

334.4 - 341.6 °F (168 - 172 °C)

Initial boiling point and boiling range

> 932 °F (> 500 °C)

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

0.0000003 kPa at 25 °C

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Soluble in hot water.

Partition coefficient (n-octanol/water)

0.46 - 0.51

Auto-ignition temperature

> 356 °F (> 180 °C)

Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Aniline derivative; para-aminophenol.
Dust explosion properties	
Kst	229 bar.m/s
Minimum ignition energy (MIE) - dust cloud	5 - 10 mJ
Molecular formula	C8H9NO2
Molecular weight	151.16
Solubility (other)	Freely soluble in ethanol and in 1 N sodium hydroxide. Soluble in methanol, dimethylformamide, ethylene dichloride, acetone, and ethyl acetate. Slightly soluble in ether. Sparingly soluble in chloroform and glycerin.
Specific gravity	1.293 at 21 °C

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Ignition sources.
Incompatible materials	Acids. Amides. Oxidizing agents.
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical, and toxicological characteristics Nausea. Vomiting. Diarrhea. Abdominal pain. Loss of appetite. Sweating. Behavior, mood, or mental changes. Irritability. Jaundice. Convulsions. Skin rash.

Delayed and immediate effects of exposure Liver damage. Kidney damage. Irregular heartbeat. Cardiovascular collapse. Swelling or fluid in the brain. Hypoglycemia. Metabolic acidosis. Blood disorders. Coma.

Cross sensitivity Rarely, persons sensitive to aspirin may be sensitive to this material as well.

Medical conditions aggravated by exposure Active alcoholism. Impaired liver function. Viral hepatitis. Impaired kidney function. Malnutrition. Glucose-6-phosphate dehydrogenase deficiency.

Acute toxicity Harmful if swallowed.

Product	Species	Test Results
Acetaminophen (CAS 103-90-2)		
Acute		
<i>Oral</i>		
LD50	Mouse	338 mg/kg
	Rat	2400 mg/kg
		1944 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Local effects		
Rabbit eye irritancy test (OECD 405) Result: Not irritant.		
Rabbit skin irritancy test (OECD 404) Result: Not irritant.		
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	

Germ cell mutagenicity Due to inconclusive data the classification criteria are not met.

Mutagenicity

Ames test in Salmonella typhimurium and E. coli
Result: Negative.
Drosophila SLRL test
Result: Negative.
In vitro tests in human cells
Result: Induced sister chromatid exchange and chromosomal aberrations.
In vitro tests in mammalian cells
Result: Induced chromosomal aberrations, micronuclei, and sister chromatid exchange; did not induce gene mutation.
In vivo cytogenetic test in mice
Result: Induced DNA single-strand breaks.
In vivo cytogenetic tests in human cells
Result: Induced sister chromatid exchange.
In vivo cytogenetic tests in mammalian cells
Result: Aneugenic; induced chromosomal aberrations; did not induce micronuclei.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans.

600 - 6000 ppm 2-year Feed studies
Result: No evidence of carcinogenetic activity in males; equivocal evidence of carcinogenetic activity in females based on increased incidences of mononuclear cell leukemia.
Species: Rat
600 - 6000 ppm 2-year Feed studies
Result: No evidence of carcinogenic activity in males and females.
Species: Mouse

Reproductive toxicity Based on available data, the classification criteria are not met. Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.

Reproductivity

0 - 250 mg/kg/day Reproductivity and development, administered orally during gestation
Result: Dose-dependent increase in malformations.
Species: Mouse
0 - 250 mg/kg/day Reproductivity and development, administered orally during gestation
Result: No fetal or embryo toxicity; no maternal toxicity; no teratogenicity.
Species: Rat
0.25 - 1 % Reproductivity - continuous breeding protocol, administered in diet
Result: No effect on fertility endpoints; reduced growth and birth weights; increased incidence of sperm abnormalities.
Species: Mouse

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects. Accumulation in aquatic organisms is expected.

Product	Species	Test Results
Acetaminophen (CAS 103-90-2)		
Aquatic		
Crustacea	EC50	Water flea (Daphnia magna) 6.1 - 14 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas) 814 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Local disposal regulations	Not available.
Hazardous waste code	Not regulated.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 04-01-2009

Revision date 06-28-2013

Version # 02

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.