

1. Identification

Product identifier	Acetaminophen	
Other means of identification		
Catalog number	1003009	
CAS number	103-90-2	
Synonyms	Paracetamol	
Chemical name	Acetamide, N-(4-hydroxyphenyl)-, 4'-hydroxyacetanilide	
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		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
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

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning	
Hazard statement	Harmful if swallowed.	
Precautionary statement		
Prevention	Wash thoroughly after handling.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.	
Storage	Not available.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	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.	
Supplemental information	Pharmacologically active material.	

3. Composition/information on ingredients

Substance

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.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. Treatment for acetaminophen overdose may include the following: 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. Administer acetylcysteine (an antidote used to protect against acetaminophen-induced hepatotoxicity) as soon as possible following an overdose. Determine plasma acetaminophen concentration at least 4 hours following ingestion of the overdose. Determinations performed prior to this time are not reliable. 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. Perform liver function tests every 24 hours for at least 96 hours post-ingestion (if the plasma acetaminophen concentration indicates potential hepatotoxicity). Monitor renal and cardiac function and administer appropriate therapy as required. Institute supportive treatment, including maintaining fluid and electrolyte balance, correcting hypoglycemia, and administering vitamin K1, fresh frozen plasma, or clotting factor concentrate if needed.
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. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding 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	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. 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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe 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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

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

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

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 available.
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(ies)	
Solubility (water)	Hot water: Soluble.
Solubility (other)	Acetone: Soluble. Chloroform: Slightly soluble. Ethanol: Freely soluble. Ether: Slightly soluble. Methanol: Soluble.
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
pH in aqueous solution	5.1 - 6.5
Specific gravity	1.29 at 21 °C

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Acids. Oxidizing agents. Alkaline metals. Amides.
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

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Harmful if swallowed.

Symptoms related to the physical, chemical, and toxicological characteristics

Gastrointestinal disturbances. Sweating. Behavior, mood, or mental changes. Irritability. Jaundice. Convulsions. Skin rash.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product	Species	Test Results
---------	---------	--------------

Acetaminophen (CAS 103-90-2)

Acute

Oral

LD50	Rat	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

Eye irritancy
Result: Negative.
Skin irritancy
Result: Negative.
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test (Salmonella typhimurium; 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 Based on available data, the classification criteria are not met.

600 - 6000 ppm Carcinogenicity
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
Test Duration: 2 years
600 - 6000 ppm Carcinogenicity
Result: No evidence of carcinogenic activity in males and females.
Species: Mouse
Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

Acetaminophen (CAS 103-90-2) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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, administered orally during gestation

Result: Dose-dependent increase in malformations.

Species: Mouse

0 - 250 mg/kg/day Reproductivity, administered orally during gestation

Result: No fetal or embryo toxicity; no maternal toxicity; no teratogenicity.

Species: Rat

0.25 - 1 % Reproductivity, 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 Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

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

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information**Ecotoxicity**

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

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

Bioaccumulative potential

Octanol/water partition coefficient log Kow

0.46 - 0.51

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions 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 Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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 dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) 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

Country(s) or region	Inventory name	On inventory (yes/no)*
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)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 04-01-2009

Revision date 10-03-2018

Version # 03

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.

Disclaimer USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.