U.S. Pharmacopeial Convention

SAFETY DATA SHEET

1. Identification

Product identifier Acetylcysteine

Other means of identification

Catalog number 1009005
CAS number 616-91-1
Synonyms N-Acetylcysteine
Chemical name L-Cysteine, N-acetyl-

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 & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.
Health hazards Not classified.
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

Hazard symbol None.
Signal word None.

Hazard statement Not available.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

s) not otherwise None known.

Hazard(s) not otherwise

classified (HNOC)

NONE KNOWN.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Acetylcysteine	N-Acetylcysteine	616-91-1	100

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

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.

Material name: Acetylcysteine

USP SDS US

Ingestion

Most important

symptoms/effects, acute and

delayed

Indication of immediate medical attention and special treatment needed

General information

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Gastrointestinal disturbances. Pharmacologically active material. Occupational exposure may cause physiological effects.

Provide general supportive measures and treat symptomatically. Acetylcysteine: Administer activated charcoal as a slurry. Support airway, maintain vital signs, and reverse bronchospasm. Epinephrine, antihistamines, and steroids may be useful. [Meditext 2008 and HSDB 2008]

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

Special protective equipment and precautions for firefighters No unusual fire or explosion hazards noted.

Wear suitable protective equipment.

Fire fighting equipment/instructions

Specific methods

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.

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. 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. 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

No exposure limits noted for ingredient(s).

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.

Material name: Acetylcysteine USP SDS US **Respiratory protection** Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters for spill cleanup. Chose 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

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 Crystalline powder.

Color White.

Odor Slight acetic odor.
Odor threshold Not available.

pH 2 - 2.8 (1% solution)

Melting point/freezing point 219.2 - 230 °F (104 - 110 °C)

Initial boiling point and boiling

range

Not available.

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 0.000002 kPa at 25 °C

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Acetone: Soluble.

Alcohol: Freely soluble.

Chloroform: Practically insoluble. Ether: Practically insoluble. Ethyl acetate: Soluble. Hot isopropyl alcohol: Soluble. Methanol: Freely soluble. Methyl acetate: Soluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical family Alpha-Amino acid.

Molecular formula C5H9NO3S

Molecular weight 163.2

Percent volatile 0 %

10. Stability and reactivity

ReactivityThe 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 Strong oxidizing agents. Metals.

Material name: Acetylcysteine USP SDS US

NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

products

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.IngestionKnowledge about health hazard is incomplete.

Symptoms related to the physical chemical and

physical, chemical, and toxicological

Gastrointestinal disturbances. Fever. Bronchospasm. Wheezing. Shortness of breath.

toxicological characteristics

Information on toxicological effects

Acute toxicity

Product	Species	Test Results		
Acetylcysteine (CAS 616-91-1)				
<u>Acute</u>				
Oral				
LD50	Dog	1 g/kg		
	Mouse	> 3 g/kg		
	Rat	3 g/kg		

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization

Skin sensitization

Knowledge about health hazard is incomplete.

Knowledge about health hazard is incomplete.

Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test (Salmonella typhimurium) Result: Negative (+/- activation) In vivo (Mouse) micronucleus test

Result: Negative.

Mouse lymphoma assay: In vitro mouse lymphoma cell

forward mutation test Result: Positive.

Mutagenicity: Chinese hamster V-79 assay

Result: Negative.

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

< 1000 mg/kg/day Carcinogenicity

Result: Not carcinogenic: No evidence of carcinogenicity.

Species: Rat

Test Duration: 12 months

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicityBased on available data, the classification criteria are not met.

Reproductivity

500 - 1000 mg/kg/day Reproduction Test

Result: Negative: No increased birth defects at 500

mg/kg/day; no evidence of impaired fertility or harm to fetus

up to 1000 mg/kg/day. Species: Rabbit

< 2000 mg/kg/day Reproduction Test

Result: Negative: No evidence of impaired fertility or harm to

fetus.

Species: Rat

Material name: Acetylcysteine USP SDS US

Reproductivity

Reproduction Test

Result: Negative: Slight decrease in the frequency of viable

fetuses and a slight increase in cleft palates.

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 The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

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

Bioaccumulative potential No data available.

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 Dispose in accordance with all applicable regulations. 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.

Local disposal regulationsDispose in accordance with all applicable regulations.

Hazardous waste codeThe 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 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

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

shipment.

Not applicable.

15. Regulatory information

US federal regulationsThis product is not known to be 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 - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

Material name: Acetylcysteine USP SDS US

SARA 311/312 Hazardous Nο

chemical

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)

Philippines

Not regulated.

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material **US** state regulations

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

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes

Philippine Inventory of Chemicals and Chemical Substances

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

04-01-2008 Issue date **Revision date** 12-26-2017

Version # 03

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herein.

Material name: Acetylcysteine USP SDS US

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).