SAFETY DATA SHEET

Product Name: ACETYLCYSTEINE - acetylcysteine solution

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	ACETYLCYSTEINE - acetylcysteine solution
Synonyms	N-acetyl-L-cysteine

2. HAZARD(S) IDENTIFICATION

Emergency Overview

ACETYLCYSTEINE - acetylcysteine solution contains N-acetyl-L-cysteine, a derivative of the naturally occurring amino acid, L-cysteine. Clinically, it is used as a mucolytic agent in respiratory disorders associated with acute cough or as an antidote to acetaminophen overdose. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the respiratory and cardiovascular systems.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage/Irritation	2B
	STOT – SE	3

Label Element(s)

Pictogram(s)

Signal Word

Warning

Hazard Statement(s)

Causes eye irritation
May cause respiratory irritation

Precautionary Statement(s)

Prevention

Wash hands thoroughly after handling
Avoid breathing vapor or spray
Use only in a well-ventilated area

Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name N-acetyl-L-cysteine
Chemical Formula $C_5H_9NO_3S$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
N-Acetyl-L-cysteine	≤20	616-91-1	HA1660000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include edetate disodium dihydrate; sodium hydroxide and/or hydrochloric acid may be added for pH adjustment.

4. FIRST AID MEASURES

Eye Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

5. FIRE FIGHTING MEASURES

Flammability None anticipated for this aqueous product.

Fire & Explosion Hazard None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
N-Acetyl-L-cysteine	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use.

Skin Protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	N-Acetyl-L-cysteine is a white crystalline powder. Product is a clear solution.
Odor	NA
Odor Threshold	NA
pH	pH 7.0 (6.0 to 7.5)
Melting point/Freezing point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	1 in 5 of water and 1 in 4 of alcohol; practically insoluble in chloroform and in ether.
Partition coefficient: n-octanol/water	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), sulfur oxides (SOx), and nitrogen oxides (NOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
N-Acetyl-L-Cysteine	100	LD50	Oral	5050 4400 >1000	mg/kg mg/kg mg/kg	Rat Mouse Dog
N-Acetyl-L-Cysteine	100	LD50	Intravenous	1140 3800 700	mg/kg mg/kg mg/kg	Rat Mouse Dog
N-Acetyl-L-Cysteine	100	LD50	Intraperitoneal	400 700	mg/kg mg/kg	Mouse Dog

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, the primary adverse effects are nausea and vomiting (especially after oral therapy). Other adverse effects may include flushing, fever, syncope, sweating, arthralgia, blurred vision, disturbances of liver function, acidosis, convulsions, and cardiac or respiratory arrest. Hemoptysis, rhinorrhea, and stomatitis have been associated with inhalation of acetylcysteine. Hypersensitivity reactions have been reported in patients receiving acetylcysteine, including bronchospasm, angioedema, rashes and pruritus; hypotension, or occasionally hypertension, may occur. Some patients experience severe anaphylactoid reactions after the intravenous use of acetylcysteine in the treatment of paracetamol poisoning. In these events, symptoms noted include rash and pruritus, flushing, nausea or vomiting, angioedema, tachycardia, bronchospasm, hypotension, and hypertension. Anaphylactoid reactions after intravenous acetylcysteine appear to be dose-related.
Aspiration Hazard	None anticipated from normal handling of this product. However, hemoptysis has been associated with inhalation of acetylcysteine.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions including bronchospasm, angioedema, rashes and pruritus; hypotension, or occasionally hypertension, have been reported in patients receiving acetylcysteine. Some patients experience severe anaphylactoid reactions after the intravenous use of acetylcysteine.

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects:

None anticipated from normal handling of this product. Teratology studies were performed in rats at oral dosages up to 2000 mg/kg/day and in rabbits at oral dosages up to 1000 mg/kg/day and revealed no evidence of impaired fertility or harm to the fetus due to acetylcysteine. A reproductive toxicity test to assess potential impairment of fertility was performed with acetylcysteine (10%) combined with isoproterenol (0.05%) and administered as an aerosol. No adverse effects were noted in dams or pups. In a teratology study of acetylcysteine in the rabbit, oral dosages of 500 mg/kg/day were given to pregnant does by intubation on days 6 through 16 of gestation. Acetylcysteine was found to be non-teratogenic under the conditions of study. In pregnant rabbits, 2 groups were exposed to an aerosol of 10% acetylcysteine and 0.05% isoproterenol HCl for 30 or 35 minutes twice a day from the 6th through the 18th day of pregnancy. No teratogenic effects were noted among the offspring.

Teratology and a perinatal and postnatal toxicity study in rats were performed with a combination of acetylcysteine and isoproterenol administered by the inhalation route. In the rat, 2 groups of 25 pregnant females each were exposed to the aerosol for 30 and 35 minutes, respectively, twice a day from the 6th through the 15th day of gestation. No teratogenic effects were observed among the offspring. In the pregnant rat, twice-daily exposure to an aerosol of acetylcysteine and isoproterenol for 30 or 35 minutes from the 15th day of gestation through the 21th day postpartum was without adverse effect on dams or newborns. Increased frequencies of fetal resorptions and cleft palate were seen when pregnant mice were treated with acetylcysteine at dosages within the human therapeutic range. This treatment also caused maternal death in some cases. In another study, the frequency of viable fetuses was slightly decreased and the frequency of fetuses with cleft palate slightly increased among the offspring of pregnant mice treated orally with twice the maximum human dose of acetylcysteine. No teratogenic effect was observed among the offspring of mice fed diets containing 0.2% acetylcysteine during pregnancy.

Mutagenicity

N-Acetyl-L-cysteine was not mutagenic in the Ames test, both with and without metabolic activation.

Carcinogenicity

Long-term oral studies of acetylcysteine in rats (12 months of treatment followed by 6 months of observation) at dosages up to 1000 mg/kg/day provided no evidence of carcinogenic activity.

Carcinogen Lists

IARC: Not listed **NTP:** Not listed **OSHA:** Not listed

Specific Target Organ Toxicity – Single Exposure

NA

Specific Target Organ Toxicity – Repeat Exposure

Based on clinical use, possible target organs include the respiratory and cardiovascular systems.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product.

Persistence/Biodegradability

Not determined for product.

Bioaccumulation

Not determined for product.

Mobility in Soil

Not determined for product.

Notes:

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt. However, acetylcysteine is listed on the TSCA inventory.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Wash hands thoroughly after handling
Avoid breathing vapor or spray
Use only in a well-ventilated area

Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

15. REGULATORY INFORMATION: continued

EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: October 17, 2012
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