

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Acetylcysteine Solution, USP**
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: September 17, 2012
SDS Revision Date: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Respiratory sensitisation. Category 1.
 Eye Irritation. Category 2.
 Skin Sensitization. Category 1.
 Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Causes serious eye irritation.
 May cause an allergic skin reaction.
 May cause respiratory irritation.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Use only outdoors or in a well-ventilated area.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 In case of inadequate ventilation wear respiratory protection.
 IF ON SKIN: Wash with plenty of water.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical advice/attention.
 Call a POISON CENTER or doctor/physician if you feel unwell.
 Specific treatment (see ... on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 If eye irritation persists: Get medical advice/attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 Store in a well-ventilated place. Keep container tightly closed.
 Store locked up.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. For Inhalation (Mucolytic Agent) using a nebulizer or Oral Administration (Acetaminophen Antidote). Not for Injection. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May be harmful if ingested.

Aggravation of Pre-Existing Conditions: None generally recognized.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
---------------	------	--------------------	---------

Acetylcysteine	616-91-1	10 - 20% (0.4 - 6 gm per vial)	
Edetate Disodium	139-33-3	0.025 - 0.05% (1 - 15 mg per vial)	
Hydrochloric acid	7647-01-0	As needed to adjust pH	
Sodium hydroxide	1310-73-2	As needed to adjust pH	215-185-5
Water for Injection	7732-18-5	quantity sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended nasal inhalation or oral administration purpose. Otherwise (such as in manufacturing), use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to
------------------------------	---

control airborne levels be low recommended exposure limits.

Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended nasal inhalation or oral administration purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions (such as in manufacturing). Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Hydrochloric acid :

Guideline ACGIH: TLV-STEL: 2 ppm(ceiling)
Guideline OSHA: OSHA PEL-STEL 5 ppm Ceiling/Peak

Sodium hydroxide :

Guideline ACGIH: TLV-Ceiling/Peak: 2 mg/m³
Belgium : OEL-TWA: 2 mg/m³

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Colorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Not established.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	6.0 to 7.5)
Molecular Formula:	Mixture
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from air and light.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acetylcysteine :

RTECS Number:	HA1660000
Ingestion:	Oral - Rat LD50: 5050 mg/kg [Details of toxic effects not reported other than lethal dose value]
Mutagenicity:	Not a mutagen as determined by the AMES test with and without metabolic activation EMS.
Reproductive Toxicity:	One study in rats illustrated reduction in fertility at 500 to 1000 mg/kg/day (2.6 to 5.2 times greater than human dose).
Teratogenicity:	Not considered teratogenic, Pregnancy Category B
Other Toxicological Information:	Intravenous. - Rat LD50: 1140 mg/kg [Gastrointestinal - Other changes] Intraperitoneal. - Mouse LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value]

Edetate Disodium :

RTECS Number:	AH4375000
Eye:	Rabbit, not irritating.
Skin:	Rabbit, not irritating.
Inhalation:	Inhalation - Rat LOAEC 30 mg/m ³ /6 h (aerosol) (OECD Guideline 412) (ECHA)
Ingestion:	Oral - Rat LD50 2800 mg/kg (ECHA)
Other Toxicological Information:	Intravenous. - Mouse LD50 : 56 mg/kg (RTEC)

Hydrochloric acid :

RTECS Number: MW4025000

Eye: Eye - Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)

Skin: Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)

Inhalation: Inhalation - Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis]
Inhalation - Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)]
Inhalation - Rat LC50: 45000 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - LC50: 0.1 gm/m3 [Details of toxic effects not reported other than lethal dose value]
Inhalation - Rat LC50: 60938 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 20487 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50: 7004 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 3940 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value]
Inhalation - Mouse LC50: 2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)

Ingestion: Oral - Rabbit LD50: 900 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Carcinogenicity: IARC 3

Sodium hydroxide :

RTECS Number: WB4900000

Eye: Eye - Rabbit Standard Draize test.: 400 ug
Eye - Rabbit Standard Draize test.: 1 %
Eye - Rabbit Standard Draize test.: 50 ug/24H
Eye - Rabbit Standard Draize test.: 1 mg/24H
Eye - Rabbit Rinsed with water.: 1 mg/30S (RTECS)

Skin: Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

Edetate Disodium :

Ecotoxicity: Guppy (Poecilia reticulata) LC50 (96hr) 320 mg/L (OECD SIDS)
Zebra fish (Danio rerio) NOEC (35d) >= 25.7 mg/L (OECD Guideline 210 , GLP) (TS : Ethylenediamintetraacetic acid, calcium disodium complex)
Water flea (Daphnia magna) EC50 (48hr) 140 mg/L, NOEC (21d) 25 mg/L (EEC Guideline XI/681/86, GLP) (TS : Ethylenediaminetetraacetic acid, disodium salt)
Green algae (Scenedesmus quadricauda) NOEC (24 d) 200 mg/L (ECHA)

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

IATA Shipping Name: Non regulated.

IATA UN Number: Non regulated.

IMDG UN Number : Non regulated.

IMDG Shipping Name : Non regulated.

SECTION 15 : REGULATORY INFORMATION**Edetate Disodium :**

TSCA Inventory Status: Listed

EINECS Number: 205-358-3

Canada DSL: Listed

Hydrochloric acid :

TSCA Inventory Status: Listed

EINECS Number: 231-595-7

SARA: EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.

Section 302 EHS: EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500 Lbs.

Section 304 RQ: EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 5,000 Lbs.

Canada DSL: Listed

Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

Sodium hydroxide :

TSCA Inventory Status: Listed

EINECS Number: 218-147-6

Canada DSL: Listed

EC Number: 215-185-5

Water for Injection :

TSCA Inventory Status: Listed

Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1
HMIS Fire Hazard: 1
HMIS Reactivity: 1
HMIS Personal Protection: X

SDS Creation Date: September 17, 2012

SDS Revision Date: June 01, 2015

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

Copyright© 1996-2015 Actio Corporation. All Rights Reserved.