SAFETY DATA SHEET
Acetylcysteine Solution, USP

SECTION 1: IDENTIFICATION

1.1 Product Identifier

Product Form : Mixture

Product Name : Acetylcysteine Solution, USP

Product Code : 10% Solution: NDC- 70069-018-25

: 20% Solution: NDC- 70069-020-03 and 70069-019-25

1.2 Intended Use of the Product

Use of the substance/mixture : **Pharmaceutical**

1.3. Name, Address, and Telephone of the Responsible Party

Company
Somerset Therapeutics, LLC.
Somerset, NJ 08873
1-800-417-9175

SECTION 2 : HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture Classification (GHS-US)

Skin Irrit. 2	H315
Eye Irrit. 2A	H319
STOT SE 3	H335
Aquatic Acute 3	H402
Full text of H-phrases:	see section 16

2.2. Label Elements GHS-US Labeling

Hazard Pictograms (GHS-US)

GHS07

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H402 - Harmful to aquatic life.

Precautionary Statements (GHS-US) : P261 - Avoid breathing vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P271 - Use only outdoors or in a well-ventilated area.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 - Call a poison center or doctor if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362 - Take off contaminated clothing and wash it before reuse.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.1. Other Hazards

May cause an allergic reaction in sensitive individuals. Some hypersensitivity reactions have been seen when this drug has been used. Photosensitivity allergic reaction has been reported by people with high blood pressure, high blood cholesterol, multiple sclerosis, depression, crohn's disease.

2.2. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	75 - 87.5	Not classified
L-Cysteine, N-acetyl-	(CAS No) 616-91-1	10 - 20	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Sodium hydroxide	(CAS No) 1310-73-2	2.5 - 5	Met. Corr. 1, H290 Skin Corr. 1A, H314Eye Dam. 1, H318 Aquatic Acute 3, H402
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS No) 6381-92-6	0.03	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation: dust, mist), H332Skin Irrit. 2, H315 Eye Irrit. 2A, H319STOT SE 3, H335 Aquatic Chronic 3, H412
Hydrochloric acid	(CAS No) 7647-01-0	*	Met. Corr. 1, H290 Acute Tox. 3 (Inhalation:gas), H331Skin Corr. 1C, H314 Eye Dam. 1, H318STOT SE 3, H335 Aquatic Acute 1, H400

*Added for pH adjustment

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice(show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice. **First-aid Measures After Inhalation**: When symptoms occur: go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical attention.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: May cause skin irritation.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, carbon dioxide, foam, dry chemical. **Caution: CO_2 will displace air in confinedspaces and may cause an oxygen deficient atmosphere.**
Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Reactivity: May react with strong oxidizers, increasing risk of fire or explosion.

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Do not breathe vapour or mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.
Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".
Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods,protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.
Storage Conditions: Store in original container. Store in a dry, cool and well-ventilated place.
Incompatible Products: Strong bases. Strong oxidizers.
Storage Temperature: 20 - 25 °C (68 - 77 °F) Excursions permitted to 15 - 30 °C (59 - 86 °F)

7.3. Specific End Use(s) Pharmaceutical.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer,supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m³)	2 mg/m³
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	2 mg/m³
USA IDLH	US IDLH (mg/m³)	10 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	2 mg/m³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	7 mg/m³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m³)	7 mg/m³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m³)	7 mg/m³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m³)	7 mg/m³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective goggles. Insufficient ventilation: wear respiratory protection.

Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection : In case of inadequate ventilation wear respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Clear, colourless to light purple colour solution, essentially free from visible extraneous matter.

Odor : Odor of Hydrogen Sulfide (rotten eggs)

Odor Threshold : No data available

pH : 6 - 7.5

Evaporation Rate : No data available

Melting Point : ≈ 0 °C (32 °F)

Freezing Point : No data available

Boiling Point : ≈ 101 °C (213.8 °F)

Flash Point : Nonflammable, Noncombustible

Auto-ignition Temperature : No data available

Decomposition Temperature : 232.22 °C (450 °F)

Flammability (solid, gas) : No data available

Vapor Pressure : No data available

Relative Vapor Density at 20 °C : No data available

Relative Density : ≈ 1 - 1.1

Solubility : Soluble in water.

Partition Coefficient: N-Octanol/Water : No data available

Viscosity : No data available

9.2. Other Information

VOC content : 0 %

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: May react with strong oxidizers, increasing risk of fire or explosion.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames; thermally decomposes to form toxic vapors.

10.5. Incompatible Materials: Strong oxidizers. Strong bases.

10.6. Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO_2). Nitrogen compounds.Irritating or toxic vapors.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Acetylcysteine Solution, USP	
Toxic Dose Minimum (TDLo)	8480 mg/kg/3D - multiple - child
LD50 Oral Rat	5050 mg/kg (7888 mg/kg - mouse)
LD50 Intravenous Rat	1140 mg/kg (3800 mg/kg intravenous - mouse; 700 mg/kg intravenous - dog)
LD50 Intraperitoneal	Mouse: 400 mg/kg; Dog: 700 mg/kg
L-Cysteine, N-acetyl- (616-91-1)	
LD50 Oral Rat	5050 mg/kg
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
ATE (Oral)	500.00 mg/kg body weight
ATE (Dermal)	1,100.00 mg/kg body weight
ATE (Dust/Mist)	1.50 mg/l/4h
Sodium hydroxide (1310-73-2)	
LD50 Dermal Rabbit	1350 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 (238 - 277) mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h)
LC50 Inhalation Rat	1411 ppm
ATE (Gases)	700.00 ppmV/4h
ATE (Dust/Mist)	0.42 mg/l/4h

Skin Corrosion/Irritation: Causes skin irritation.
pH: 6 - 7.5
Serious Eye Damage/Irritation: Causes serious eye irritation.
pH: 6 - 7.5
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified (Not a mutagen as determined by the AMES test with and without metabolic activation EMS)
Carcinogenicity: Not classified

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Not classified (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); Not considered teratogenic, Pregnancy Category B. One animal study reported EDTA as a teratogenic agent; US FDA Pharmaceutical Pregnancy Category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in anytrimester)
Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l
Hydrochloric acid (7647-01-0)	
EC50 Daphnia 1	0.492 mg/l

12.2. Persistence and Degradability

Acetylcysteine Solution, USP	
Persistence and Degradability	Degradation is expected under aerobic and anaerobic conditions. Short term products of biodegradation may be more toxic or hazardous than product.

12.3. Bioaccumulative Potential No additional information available

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Acetylcysteine Solution, USP	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
L-Cysteine, N-acetyl- (616-91-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventoryListed on the United States SARA Section 302 Listed on United States SARA Section 313	
SARA Section 302 Threshold Planning Quantity (TPQ)	500 (gas only)
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

15.2 US State Regulations

Sodium hydroxide (1310-73-2)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List
Hydrochloric acid (7647-01-0)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 14.11.2024

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200. Acetylcysteine Solution, USP, administered orally, is indicated as an antidote to prevent or lesson hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen. It is essential to initiate treatment as soon as possible after the overdose and, in any case, within 24 hours of ingestion. When administered via inhalation it is indicated as adjuvant therapy for patients with abnormal, viscid or inspissated mucous secretions in various respiratory conditions. Refer to Somerset Therapeutics Private Limited's prescribing information for further information at Somerset Therapeutics Private Limited.

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation: gas)	Acute toxicity (inhalation: gas) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation: dust, mist)	Acute toxicity (inhalation: dust, mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1C	Skin corrosion/irritation Category 1C
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

Refer to Somerset Therapeutics Private Limited prescribing information for further information.

The information above is believed to be accurate and represents the best information currently available to Somerset Therapeutics Private Limited. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Somerset Therapeutics Private Limited, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Somerset Therapeutics Private Limited. has been advised of the possibility of such damages.

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