

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form** Solution

**Product Name:** Acetylcysteine Solution, USP

**Product Code:** 10% Solution: 0517-7504-25; 0517-7510-03

20% Solution: 0517-7604-25; -0517-7610-03; 0517-7630-03

### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Acetylcysteine Solution, USP, administered orally, is indicated as an antidote to prevent or lessen 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.

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

#### Company

Luitpold Pharmaceuticals, Inc.

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

[www.luitpold.com](http://www.luitpold.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

## 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)



#### 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.

# Acetylcysteine Solution, USP

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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.

### 2.3. Other Hazards

Exposure to acetylcysteine may result in gastrointestinal symptoms such as nausea and vomiting as well as stomatitis, fever, rhinorrhea, drowsiness, clamminess, chest tightness, rash and bronchoconstriction. Exposure may cause an allergic reaction in sensitive individuals. Acquired sensitization has been reported. See package insert for additional information.

### 2.4. 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 for Injection     | (CAS No) 7732-18-5 | 75 - 87.5              | Not classified  |
| Acetylcysteine          | (CAS No) 616-91-1  | 10 - 20                | Skin Irrit. 2, H315<br>Eye Irrit. 2A, H319<br>STOT SE 3, H335   |
| Sodium hydroxide        | (CAS No) 1310-73-2 | 2.5 - 5                | Met. Corr. 1, H290<br>Skin Corr. 1A, H314<br>Eye Dam. 1, H318<br>Aquatic Acute 3, H402  |
| Edetate disodium - EDTA | (CAS No) 6381-92-6 | 0.03                   | Acute Tox. 4 (Oral), H302<br>Acute Tox. 4 (Dermal), H312<br>Acute Tox. 4 (Inhalation:dust,mist), H332<br>Skin Irrit. 2, H315<br>Eye Irrit. 2A, H319<br>STOT SE 3, H335<br>Aquatic Chronic 3, H412 |
| Hydrochloric acid       | (CAS No) 7647-01-0 | Used for pH adjustment | Met. Corr. 1, H290<br>Acute Tox. 3 (Inhalation:gas), H331<br>Skin Corr. 1C, H314<br>Eye Dam. 1, H318<br>STOT SE 3, H335<br>Aquatic Acute 1, H400  |

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 attention (show the label where possible). In the event of accidental injection, immediately call a poison center and seek medical attention.

**First-aid Measures After Inhalation:** 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. Seek medical attention.

### 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.

# Acetylcysteine Solution, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## 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<sub>2</sub> will displace air in confined spaces 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 vapor 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 a dry, well ventilated place at 20 - 25 °C (68 - 77 °F) away from direct sunlight and incompatible materials.

**Incompatible Products:** Strong bases. Strong oxidizers.

### 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/m <sup>3</sup> )       | 2 mg/m <sup>3</sup>  |
| USA NIOSH                    | NIOSH REL (ceiling) (mg/m <sup>3</sup> ) | 2 mg/m <sup>3</sup>  |
| USA IDLH                     | US IDLH (mg/m <sup>3</sup> )             | 10 mg/m <sup>3</sup> |
| USA OSHA                     | OSHA PEL (TWA) (mg/m <sup>3</sup> )      | 2 mg/m <sup>3</sup>  |

# Acetylcysteine Solution, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

| 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/m <sup>3</sup> ) | 7 mg/m <sup>3</sup>                    |
| USA NIOSH                     | NIOSH REL (ceiling) (ppm)                | 5 ppm                                  |
| USA IDLH                      | US IDLH (ppm)                            | 50 ppm                                 |
| USA OSHA                      | OSHA PEL (Ceiling) (mg/m <sup>3</sup> )  | 7 mg/m <sup>3</sup>                    |
| 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, colorless solution (may have a slight purple color after opening) |
| Odor                                   | : Odor of hydrogen sulfide (rotten eggs)                                   |
| Odor Threshold                         | : No data available  |
| pH                                     | : 6.0 - 7.5  |
| Evaporation Rate                       | : No data available  |
| Melting Point                          | : No data available  |
| Freezing Point                         | : No data available  |
| Boiling Point                          | : No data available  |
| Flash Point                            | : Nonflammable, Noncombustible   |
| Auto-ignition Temperature              | : No data available  |
| Decomposition Temperature              | : No data available  |
| Flammability (solid, gas)              | : No data available  |
| Vapor Pressure                         | : No data available  |
| Relative Vapor Density at 20 °C        | : No data available  |
| Specific Gravity                       | : ≈ 1.0 - 1.1  |
| Solubility                             | : Aqueous solution   |
| 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.

# Acetylcysteine Solution, USP

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

**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<sub>2</sub>). 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   |
| Acetylcysteine (616-91-1)           |  |
| LD50 Oral Rat                       | 5050 mg/kg   |
| Edetate disodium - EDTA (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: 6.0 - 7.5

**Serious Eye Damage/Irritation:** Causes serious eye irritation.

pH: 6.0 - 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 or 5.2 times the human mucolytic dose). Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

**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   |
|                              |   |

### 12.2. Persistence and Degradability

| Acetylcysteine Solution, USP  |  |
|-------------------------------|--|
| Persistence and Degradability | Degradation is expected under aerobic and anaerobic conditions. Short term |

# Acetylcysteine Solution, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

|   |
|---|
| 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**

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

**15.2 US State Regulations**

|   |
|---|
| <b>Sodium hydroxide (1310-73-2)</b>                                   |
| 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                        |
| <b>Hydrochloric acid (7647-01-0)</b>                                  |
| 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** : 11/12/2015

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**GHS Full Text Phrases:**

|                               |  |
|-------------------------------|--|
| Acute Tox. 3 (Inhalation:gas) | Acute toxicity (inhalation:gas) Category 3 |
| Acute Tox. 4 (Dermal)         | Acute toxicity (dermal) Category 4         |

# Acetylcysteine Solution, USP

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

|                                     |  |
|-------------------------------------|--|
| 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 Luitpold/American Regent prescribing information for further information at:  
<http://www.americanregent.com/AllProducts.aspx>

*The information above is believed to be accurate and represents the best information currently available to American Regent. 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 Luitpold, 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 Luitpold has been advised of the possibility of such damages.*

SDS US (GHS HazCom)