1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Acetylcysteine Solution (Hospira Inc.)
Trade Name: ACETYLCYSTEINE Solution, USP
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet
Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification: Not classified as hazardous

Label Elements
Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous
SAFETY DATA SHEET

Material Name: Acetylcysteine Solution (Hospira Inc.)
Revision date: 31-Jan-2019
Version: 1.1

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr.1B (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3 (H335)</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Acetylcysteine</td>
<td>616-91-1</td>
<td>210-498-3</td>
<td>Not Listed</td>
<td>10 or 20</td>
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<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Disodium EDTA (dihydrate)</td>
<td>6381-92-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures:

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: As for primary cause of fire.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable
Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use with adequate ventilation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Acetylcysteine
Pfizer OEL TWA-8 Hr: 3000µg/m³

Sodium hydroxide
ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Type</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slovenia</td>
<td>OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden</td>
<td>OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

**HYDROCHLORIC ACID**

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Type</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany - TRGS 900</td>
<td>TWAs</td>
<td>2 ppm</td>
</tr>
<tr>
<td>Germany (DFG)</td>
<td>MAK</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>France - MAKs</td>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td></td>
<td>2 ppm</td>
</tr>
<tr>
<td>Latvia</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Lithuania</td>
<td>OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Malta</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Netherlands</td>
<td>OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Romania</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Slovakia</td>
<td>OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovenia</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Spain</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Switzerland</td>
<td>OEL - TWAs</td>
<td>2 ppm</td>
</tr>
</tbody>
</table>

Revision date: 31-Jan-2019
SAFETY DATA SHEET

Material Name: Acetylcysteine Solution (Hospira Inc.)
Revision date: 31-Jan-2019

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory Protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Odor: Not applicable
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: Soluble
pH: 7.0 (6.0-7.5)
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Water for injection No data available
Sodium hydroxide No data available
Acetylcysteine No data available

HYDROCHLORIC ACID
No data available
Disodium EDTA (dihydrate)
No data available
Decomposition Temperature (°C): No data available.
SAFETY DATA SHEET

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
  Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
  Hazardous Decomposition Products: Nitrogen oxides (nox), Sulphur oxides, Oxides of carbon.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye and skin irritation. Not acutely toxic (based on components).
Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include nausea, vomiting, fever, drowsiness, tightness of chest, hypersensitivity reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Acetylcysteine
Rat Oral LD50 > 6000 mg/kg
Rat Para-periosteal LD50 1140mg/kg
Mouse Oral LD50 > 3000mg/kg
Mouse Intravenous LD50 3800mg/kg
Mouse Intraperitoneal LD50 400mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide

PZ03245
11. TOXICOLOGICAL INFORMATION

Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

**Acetylcysteine**
- Reproductive & Fertility  Rat  Oral  1000 mg/kg/day  NOAEL  No effects at maximum dose
- Embryo / Fetal Development  Rabbit  Oral  500 mg/kg/day  NOAEL  Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

**Acetylcysteine**
- Bacterial Mutagenicity (Ames)  *Salmonella, E. coli*  Negative
  - *In Vivo* Micronucleus  Negative
  - *In Vitro* Forward Mutation Assay  Positive

**HYDROCHLORIC ACID**
- Bacterial Mutagenicity (Ames)  *Salmonella*  Negative
- *In Vivo* Micronucleus  Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Acetylcysteine**
- 18 Month(s)  Rat  Oral  1000 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**HYDROCHLORIC ACID**
- IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:  No data available

Persistence and Degradability:  No data available

Bio-accumulative Potential:  No data available

Mobility in Soil:  No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Acetylcysteine

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
- EU EINECS/ELINCS List: 210-498-3

Water for injection

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register:
- EU EINECS/ELINCS List: 231-791-2

Sodium hydroxide

- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 1000 lb
  - 454 kg
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category/Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCHLORIC ACID</td>
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</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<tr>
<td>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</td>
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<tr>
<td>CERCLA/SARA - Section 302 Extremely Hazardous TPQs</td>
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<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 5</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-185-5</td>
</tr>
</tbody>
</table>

| Disodium EDTA (dihydrate)                          |                   |
| CERCLA/SARA 313 Emission reporting                | Not Listed        |
| California Proposition 65                          | Not Listed        |
| Australia (AICS):                                  | Present           |
| EU EINECS/ELINCS List                              | Not Listed        |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity.

Revision date: 31-Jan-2019


Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet