



# MATERIAL SAFETY DATA SHEET

Revision date: 25-Oct-2006

Version: 1.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Acetylcysteine Solution for Inhalation/Installation**

**Trade Name:** Mucoporetta  
**Chemical Family:** Not determined  
**Intended Use:** Mucolytic; Acetaminophen Antidote

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Acetylcysteine	616-91-1	210-498-3	20
Sodium hydroxide	1310-73-2	215-185-5	**

Ingredient	CAS Number	EU EINECS List	%
Water for injection	7732-18-5	231-791-2	*
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	*
Tetrasodium EDTA	64-02-8	200-573-9	*

**Additional Information:** \* Proprietary  
\*\* to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Solution  
**Signal Word:** None required

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Eye Contact:** May cause eye irritation (based on components)  
**Skin Contact:** May cause skin irritation (based on components).  
**Inhalation:** An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). See 'Known clinical effects', below.

**Ingestion:** Not acutely toxic (based on components)  
**Known Clinical Effects:** Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache. Clinical use has caused symptoms of asthma.

**Potential Health Effects:** Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

**EU Indication of danger:** Not classified

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**Additional Information:  
Note:**

For a more detailed discussion of potential health hazards and toxicity see Section 11. This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

- Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. 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.

### 5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

- Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- Measures for Cleaning / Collecting:** Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Additional Consideration for Large Spills:** Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate container for disposal.

### 7. HANDLING AND STORAGE

- General Handling:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.
- Storage Conditions:** Store in a cool, dry, well-ventilated area. Protect from light.
- Storage Temperature:** 2-8°C (36-46°F)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Sodium hydroxide

OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
ACGIH Ceiling Threshold Limit:	= 2 mg/m <sup>3</sup> Ceiling
Australia PEAK	= 2 mg/m <sup>3</sup> Peak

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

#### Personal Protective Equipment:

<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection:</b>	Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Solution	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers.

### 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

##### Tetrasodium EDTA

Mouse	Oral	LD50	30 mg/kg
Rat	Oral	LD50	> 2000 mg/kg

##### Ascorbic acid (Vitamin C)

Rat	Oral	LD 50	11.9 g/kg
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##### Acetylcysteine

Rat	Oral	LD50	> 6000 mg/kg
Rat	Intravenous	LD50	1140 mg/kg
Mouse	Oral	LD50	> 3000 mg/kg

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Mouse Intravenous LD50 3800 mg/kg  
Mouse Intraperitoneal LD50 400 mg/kg

### Sodium hydroxide

Mouse IP LD50 40 mg/kg

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

#### Tetrasodium EDTA

Skin Irritation Rabbit Moderate  
Eye Irritation Rabbit Moderate

#### Sodium hydroxide

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 NOEL Fertility  
Embryo / Fetal Development Rabbit Oral 500 mg/kg/day NOEL Not Teratogenic

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

#### Acetylcysteine

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

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

#### Acetylcysteine

18 Month(s) Rat Oral 1000 mg/kg/day NOEL Not carcinogenic

**Carcinogen Status:** Not listed as a carcinogen by IARC, NTP or US OSHA.

## 12. ECOLOGICAL INFORMATION

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

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

## 14. TRANSPORT INFORMATION

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

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## 15. REGULATORY INFORMATION

EU Symbol: None required  
EU Indication of danger: Not classified

OSHA Label:  
None required  
Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

WHMIS hazard class:  
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Acetylcysteine

Inventory - United States TSCA - Sect. 8(b)	Present
EU EINECS List	210-498-3
Standard for the Uniform Scheduling for Drugs and Poisons - Schedule 2:	in preparations for oral use except when labeled with a recommended daily dose of $\leq 1$ g of acetylcysteine
Standard for the Uniform Scheduling for Drugs and Poisons - Schedule 4:	except when included in Schedule 2 or in preparations for oral use when labeled with a recommended daily dose of $\leq 1$ g of acetylcysteine

#### Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
EU EINECS List	231-791-2

#### Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
EU EINECS List	215-185-5
Standard for the Uniform Scheduling for Drugs and Poisons - Schedule 5:	$\leq 5\%$ except its salts and derivatives. In preparations being: solid preparations the PH of which in a 10 g/L aqueous solution is $>11.5$ , liquid or semi-solid preparations the PH of which is $>11.5$
Standard for the Uniform Scheduling for Drugs and Poisons - Schedule 6:	except its salts and derivatives. Except when included in Schedule 5, or preparations containing $\leq 5\%$ of potassium hydroxide being: solid preparations the PH of which in a 10 g/L aqueous solution is $\leq 11.5$ , or liquid or semi-solid preparations the PH of w

#### Ascorbic acid (Vitamin C)

Inventory - United States TSCA - Sect. 8(b)	Present
EU EINECS List	200-066-2

#### Tetrasodium EDTA

Inventory - United States TSCA - Sect. 8(b)	Present
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EU EINECS List

200-573-9

### 16. OTHER INFORMATION

**Prepared by:**

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

**End of Safety Data Sheet**