



# MATERIAL SAFETY DATA SHEET

Revision date: 08-Nov-2006

Version: 1.3

Page 1 of 6

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

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CHEMTREC (24 hours): 1-800-262-8200

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

### Material Name: Acetylcysteine Effervescent Tablets

**Trade Name:** Mucoporetta  
**Chemical Family:** Not determined  
**Intended Use:** Treatment of chronic bronchitis

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Acetylcysteine	616-91-1	210-498-3	200 mg***
Citric acid	77-92-9	201-069-1	*
Sodium carbonate	497-19-8	207-838-8	*

Ingredient	CAS Number	EU EINECS List	%
Sodium bicarbonate	144-55-8	205-633-8	*
Mannitol	69-65-8	200-711-8	*
Sodium saccharin	128-44-9	204-886-1	*
Lactose Monohydrate	64044-51-5	Not listed	*

### Additional Information:

\* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Tablet  
**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).  
**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

## MATERIAL SAFETY DATA SHEET

Material Name: Acetylcysteine Effervescent Tablets  
Revision date: 08-Nov-2006

Page 2 of 6  
Version: 1.3

**Additional Information:** For a more detailed discussion of potential health hazards and toxicity see Section 11.  
**Note:** 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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

## MATERIAL SAFETY DATA SHEET

Material Name: Acetylcysteine Effervescent Tablets  
Revision date: 08-Nov-2006

Page 3 of 6  
Version: 1.3

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

**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:**

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** 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>	Tablet	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**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.

### 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)**

**Sodium bicarbonate**

Rat Oral LD50 4220 mg/kg  
Mouse Oral LD50 3360 mg/kg  
Rat Inhalation LC50 > 900 mg/m<sup>3</sup>

**Mannitol**

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

**Sodium saccharin**

Mouse Oral LD50 17.5 g/kg  
Rat Oral LD50 14.2 - 17 g/kg  
Rat Intraperitoneal LD50 7100 mg/kg

**Lactose Monohydrate**

Rat Oral LD 50 29700 mg/kg

## MATERIAL SAFETY DATA SHEET

Material Name: Acetylcysteine Effervescent Tablets  
Revision date: 08-Nov-2006

Page 4 of 6  
Version: 1.3

### Acetylcysteine

Rat Oral LD50 > 6000 mg/kg  
Rat Intravenous LD50 1140 mg/kg  
Mouse Oral LD50 > 3000 mg/kg  
Mouse Intravenous LD50 3800 mg/kg  
Mouse Intraperitoneal LD50 400 mg/kg

### Citric acid

Rat Oral LD50 3000 mg/kg

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

#### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

### Sodium saccharin

36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder  
54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

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

#### Acetylcysteine

Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL Fertility  
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

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

#### Acetylcysteine

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

Carcinogen Status: See below

#### Sodium saccharin

IARC: Group 3

## 12. ECOLOGICAL INFORMATION

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

## 13. DISPOSAL CONSIDERATIONS

# MATERIAL SAFETY DATA SHEET

Material Name: Acetylcysteine Effervescent Tablets  
Revision date: 08-Nov-2006

Page 5 of 6  
Version: 1.3

**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.

## 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
Australia (AICS):	Present
EU EINECS List	210-498-3

#### Sodium bicarbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-633-8

#### Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

#### Citric acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

#### Sodium saccharin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1

## MATERIAL SAFETY DATA SHEET

Material Name: Acetylcysteine Effervescent Tablets  
Revision date: 08-Nov-2006

Page 6 of 6  
Version: 1.3

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### Lactose Monohydrate

Australia (AICS): Present

### Sodium carbonate

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

Australia (AICS): Present

EU EINECS List 207-838-8

## 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**