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

**Pfizer Inc**
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

**Pfizer Ltd**
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
ChemSafe (24 hours): +44 (0)208 762 8322
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: SOLUGASTRIL Tablets

- **Trade Name:** SOLUGASTRIL
- **Chemical Family:** Not determined
- **Intended Use:** Pharmaceutical product for the treatment of heartburn, gastrointestinal disorders

2. HAZARDS IDENTIFICATION

**Appearance:** White tablets

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

**Additional Hazard Information:**
- **Short Term:** Dust may cause irritation if tablets are crushed or broken. Acute toxicity following ingestion is not expected.
- **Known Clinical Effects:** Aluminum hydroxide may cause nausea, vomiting, and constipation. Large doses can cause intestinal obstruction.
- **EU Indication of danger:** Not classified

**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.

3. COMPOSITION/INFORMATION ON INGREDIENTS
### Hazardous Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>1317-65-3</td>
<td>215-279-6</td>
<td>Not Listed</td>
<td>600***</td>
</tr>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>244-492-7</td>
<td>Not Listed</td>
<td>12.5***</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>EEC No. 418-260-2</td>
<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium cyclamate</td>
<td>139-05-9</td>
<td>205-348-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

### 4. FIRST AID MEASURES

**Eye Contact:**  
Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**  
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:**  
Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:**  
Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**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.

### 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:**  
Not applicable

### 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:**  
Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

PZ00731
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: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Calcium carbonate
- Australia TWA = 10 mg/m³ TWA
- Belgium OEL - TWA = 10 mg/m³ TWA
- Bulgaria OEL - TWA = 1.0 l/cm³ TWA containing <2% uncombined silicon dioxide = 10.0 mg/m³ TWA
- Czech Republic OEL - TWA = 10.0 mg/m³ TWA
- Estonia OEL - TWA = 10 mg/m³ TWA
- = 5 mg/m³ TWA
- France OEL - TWA = 10 mg/m³ VME
- Greece OEL - TWA = 10 mg/m³ TWA
- = 5 mg/m³ TWA
- Hungary OEL - TWA = 10 mg/m³ TWA
- Ireland OEL - TWAs = 10 mg/m³ TWA
- = 4 mg/m³ TWA
- Netherlands OEL - TWA = 10 mg/m³ MAC
- OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total = 5 mg/m³ TWA
- Portugal OEL - TWA = 10 mg/m³ TWA
- Slovakia OEL - TWA = 10 mg/m³ TWA

Aluminum hydroxide
- ACGIH OELs - Notice of Intended Changes Listed
- Bulgaria OEL - TWA = 1.5 mg/m³ TWA
- = 10.0 mg/m³ TWA
- Czech Republic OEL - TWA = 10.0 mg/m³ TWA except for gamma Al2O3
- Latvia OEL - TWA = 6 mg/m³ TWA
- Lithuania OEL - TWA = 6 mg/m³ IPRV
- Poland OEL - TWA = 1.2 mg/m³ NDS
- = 2.5 mg/m³ NDS
- Slovakia OEL - TWA = 1.5 mg/m³ TWA

Polyethylene glycol
- Austria OEL - MAKs = 1000 mg/m³ MAK
- Germany - TRGS 900 - TWAs = 1000 mg/m³ TWA
- Netherlands OEL - TWA = 1000 mg/m³ MAC
- Slovakia OEL - TWA = 1000 mg/m³ TWA
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:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

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

Sodium cyclamate
- Rat Oral LD50 1280 mg/kg

Starch
- Mouse IP LD50 6600 mg/kg

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

Polyethylene glycol
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

Sodium cyclamate
- IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.
14. TRANSPORT INFORMATION
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class: None required

<table>
<thead>
<tr>
<th>Substance</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>215-279-6</td>
</tr>
<tr>
<td>Sodium cyclamate</td>
<td>Present</td>
<td>Present</td>
<td></td>
<td>205-348-9</td>
</tr>
<tr>
<td>Aluminum hydroxide</td>
<td>Present</td>
<td>Present</td>
<td></td>
<td>244-492-7</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>XU</td>
<td>Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mannitol</td>
<td>Present</td>
<td>Present</td>
<td></td>
<td>200-711-8</td>
</tr>
</tbody>
</table>
16. OTHER INFORMATION

Data Sources:  Publicly available toxicity information. Safety data sheets for individual ingredients.

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet