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
Contact E-Mail: Pfizer-MSDS@pfizer.com

Material Name: SOLUGASTRIL Gel

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

2. HAZARDS IDENTIFICATION

Appearance: Gel

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

Additional Hazard Information:

Short Term: May cause eye irritation (based on components). May cause allergic reactions in susceptible individuals. 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
Material Name: SOLUGASTRIL Gel
Revision date: 20-Dec-2007

Hazardous

<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>600mg/10g</td>
</tr>
<tr>
<td>Aluminum hydroxide</td>
<td>21645-51-2</td>
<td>244-492-7</td>
<td>Not Listed</td>
<td>435mg/10g</td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>EEC No. 418-260-2</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Bergamot oil</td>
<td>8007-75-8</td>
<td>Not listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F;R11</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

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

For the full text of the R phrases mentioned in this Section, see Section 16

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: 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.

PZ00738
Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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: Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

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

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 f/cm³ TWA containing &lt;2% uncombined silicon dioxide</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>10.0 mg/m³ TWA</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 mg/m³ TWA</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>4 mg/m³ TWA</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>10 mg/m³ MAC</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³ TWA total</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Aluminum hydroxide

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH OELs - Notice of Intended Changes</td>
<td>Listed</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>1.5 mg/m³ TWA</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³ TWA</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>10.0 mg/m³ TWA except for gamma Al2O3</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>6 mg/m³ TWA</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>6 mg/m³ IPRV</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1.2 mg/m³ NDS</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1.5 mg/m³ TWA</td>
</tr>
</tbody>
</table>
Silicon dioxide, NF

Australia TWA = 2 mg/m³ TWA
Austria OEL - MAKs = 4 mg/m³ MAK
Czech Republic OEL - TWA = 0.1 mg/m³ TWA
                      = 4.0 mg/m³ TWA
Estonia OEL - TWA = 2 mg/m³ TWA
Germany - TRGS 900 - TWAs = 4 mg/m³ TWA
Ireland OEL - TWAs = 2.4 mg/m³ TWA
                      = 6 mg/m³ TWA
Latvia OEL - TWA = 1 mg/m³ TWA containing more than 70% SiO₂ (quartz)
                      = 2 mg/m³ TWA containing 10-70% SiO₂ (granite, mica)
                      = 4 mg/m³ TWA containing 2-10% SiO₂ (copper sulfate ores)
OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO₂) mg/m³ TWA
                      = 20 mppcf TWA
Slovakia OEL - TWA = 4.0 mg/m³ TWA
Slovenia OEL - TWA = 4 mg/m³ TWA

Ethanol

ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1000 ppm TWA
                      = 1880 mg/m³ TWA
Austria OEL - MAKs = 1000 ppm MAK
                      = 1900 mg/m³ MAK
Belgium OEL - TWA = 1000 ppm TWA
                      = 1907 mg/m³ TWA
Bulgaria OEL - TWA = 1000.0 mg/m³ TWA
Czech Republic OEL - TWA = 1000 mg/m³ TWA
Denmark OEL - TWA = 1000 ppm TWA
                      = 1900 mg/m³ TWA
Estonia OEL - TWA = 1000 mg/m³ TWA
                      = 500 ppm TWA
Finland OEL - TWA = 1000 ppm TWA
                      = 1900 mg/m³ TWA
France OEL - TWA = 1000 ppm VME
                      = 1900 mg/m³ VME
Germany - TRGS 900 - TWAs = 500 ppm TWA
                      = 960 mg/m³ TWA
Greece OEL - TWA = 1000 ppm TWA
                      = 1900 mg/m³ TWA
Hungary OEL - TWA = 1900 mg/m³ TWA
Ireland OEL - TWAs = 1000 ppm TWA
                      = 1900 mg/m³ TWA
Latvia OEL - TWA = 1000 mg/m³ TWA
Lithuania OEL - TWA = 1000 mg/m³ IPRV
                      = 500 ppm IPRV
Netherlands OEL - TWA = 1000 mg/m³ MAC
                      = 500 ppm MAC
OSHA - Final PELS - TWAs: = 1000 ppm TWA
Poland OEL - TWA = 1900 mg/m³ TWA
Portugal OEL - TWA = 1000 ppm TWA
Romania OEL - TWA = 1000 ppm TWA
                      = 1900 mg/m³ TWA
MATERIAL SAFETY DATA SHEET

Material Name: SOLUGASTRIL Gel
Revision date: 20-Dec-2007

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>Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>No data available.</td>
</tr>
<tr>
<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)

Ethanol
Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060 mg/kg

Mouse Inhalation LC50 4h 39 g/m³
Rat Inhalation LC50 10h 20,000 ppm

Vanillin
Rat Oral LD 50 1580 mg/kg
Potassium sorbate
Rat  Oral  LD 50  4.34 gm/kg

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

Ethanol
Eye Irritation  Rabbit  Severe

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethanol
Fingerling Trout  NPDES  LC50  24 Hours  11,200 mg/L
Rainbow Trout  NPDES  LC50  96 Hours  12,900 mg/L
Fathead minnow  NPDES  LC50  96 Hours  14,200 mg/L

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

Calcium carbonate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
215-279-6

Aluminum hydroxide
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 244-492-7

Silicon dioxide, NF
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-545-4

Vanillin
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 204-465-2

Water, purified
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

Hydroxyethyl cellulose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Methylparaben
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Bergamot oil
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5

Potassium sorbate

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.

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