MATERIAL SAFETY DATA SHEET

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

Material Name: Glucotrol XL® (Glipizide) Extended Release Tablets

Trade Name: GLUCOTROL XL®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for antidiabetic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glipizide</td>
<td>29094-61-9</td>
<td>249-427-6</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene oxide NF</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: 2.5 mg: Round, biconvex, blue coated tablet 5 mg and 10 mg: Round, biconvex, white coated tablet
Signal Word: WARNING

Statement of Hazard: Antidiabetic drug: has blood-sugar lowering properties
Additional Hazard Information: Ingestion of this material may cause effects similar to those seen in clinical use including effects on gastrointestinal disturbances, allergic skin reactions, blood system changes, liver effects, kidney effects, and endocrine reactions. Overdosage of sulfonylureas can produce hypoglycemia which characterized by hunger, nervousness, profuse sweating, faintness, and sometimes convulsions.

Known Clinical Effects: Not classified
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 contaminated clothing and shoes. Wash 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 immediately. 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 immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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.

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature: Store as directed by product packaging.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glipizide
Pfizer OEL TWA-8 Hr: 0.2 mg/m³

Ferric oxide red
OSHA - Final PELS - TWAs:
= 10 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
Australia TWA = 5 mg/m³ TWA

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. 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:

Physical State: Tablet
Color: Blue (2.5 mg) White (5 and 10 mg)
Molecular Formula: Mixture
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: None known
Hazardous Decomposition Products: None known
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION
MATERIAL SAFETY DATA SHEET

Material Name: Glucotrol XL® (Glipizide) Extended Release Tablets
Revision date: 02-Jan-2007
Version: 2.7

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

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

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Sodium chloride
- Rat Oral LD50 3000 mg/kg
- Mouse Oral LD 50 4000 mg/kg

Glipizide
- Mouse Oral LD50 > 5000 mg/kg
- Rat Oral LD50 > 4000 mg/kg

Hypermellose
- Rat Oral LD50 > 10,000 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.

Inhalation Acute Toxicity
No data available

Ingestion Acute Toxicity
- No data available
- See Acute toxicity table

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

Polyethylene oxide NF
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

Sodium chloride
- Eye Irritation Rabbit Moderate
- Skin Irritation Rabbit Mild

Eye Irritation / Sensitization
- No data available

Skin Irritation / Sensitization
- No data available

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride
- 10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

Glipizide
- 6 Month(s) Rat Oral 8 mg/kg/day NOAEL No effects at maximum dose
- 10 Month(s) Dog Oral 8 mg/kg/day NOAEL No effects at maximum dose
- 15 Month(s) Rat Oral 8 mg/kg/day NOAEL No effects at maximum dose
- 40 Month(s) Dog Oral 8 mg/kg/day NOAEL No effects at maximum dose

Subchronic Effects
Subchronic toxicity was evaluated in rats at oral doses up to 8 mg/kg/day for six months. Findings revealed no drug-related toxicity. A ten month oral study on dogs at doses up to 8 mg/kg/day showed no drug-related toxicological or pathological changes.

Chronic Toxicity
Chronic toxicity was evaluated in rats at dose levels up to 50 mg/kg/day for 18 months. High dosed animals exhibited mild to moderate increases in SGOT levels. A 40 month study in dogs showed no drug-related effects at dose levels up to 8 mg/kg/day.

Chronic Effects/Carcinogenicity
No evidence of carcinogenicity was seen for glipizide in an 18-month oral study in mice and a 24-month oral study in rats at dose levels up to 50 mg/kg/day.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
Material Name: Glucotrol XL® (Glipizide) Extended Release Tablets
Revision date: 02-Jan-2007
Version: 2.7

Reproductive Effects
No effects on fertility, general reproductive performance, or fetal development were observed in rats. No drug-related effects on developmental behavior or reproductive performance were seen in rats offspring.

Teratogenicity
No evidence of embryotoxic or teratogenic effects was observed in rats at dose levels up to 2000 mg/kg/day. No evidence of teratogenic effects was seen in rabbits at dose levels up to 10 mg/kg/day.

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

Glipizide
Bacterial Mutagenicity (Ames) Salmonella Negative
In Vivo Cytogenetics Mouse Negative
Dominant Lethal Assay Mouse Negative

Mutagenicity
No evidence of mutagenic or clastogenic activity in in vitro or in vivo tests.

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

Glipizide
24 Month(s) Rat Oral 50 mg/kg/day NOAEL Not carcinogenic
18 Month(s) Mouse Oral 50 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. See below

Ferric oxide red
IARC: Group 3

At increase risk from exposure: Individuals who have shown hypersensitivity to the drug and individuals with cardiac conditions, and liver and kidney impairment may be susceptible to the toxicity of overexposure.

12. ECOLOGICAL INFORMATION

Environmental Overview: The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment. See Aquatic toxicity data of the active ingredient, below:

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

Glipizide
Daphnia Magna LC50 48 Hours > 370 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

13. DISPOSAL CONSIDERATIONS
Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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:
WARNING
Antidiabetic drug: has blood-sugar lowering properties

Canada - WHMIS: Classifications

WHMIS hazard class: None required
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.

Glipizide
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS List: 249-427-6

Ferric oxide red
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present

Polyethylene oxide NF
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present

Sodium chloride
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 231-598-3

Hypromellose
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory 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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet