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

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

Material Name: Glipizide tablets

Trade Name: GLUCOTROL; GLIBENESE; MINIDIAB
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antidiabetic agent.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Glipizide	29094-61-9	249-427-6	2.5
Starch	9005-25-8	232-679-6	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Stearic acid	57-11-4	200-313-4	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: White diamond-shaped tablets
Signal Word: WARNING

Statement of Hazard: Antidiabetic drug: has blood-sugar lowering properties
Additional Hazard Information:
Known Clinical Effects: 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.
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 product or its ingredients 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 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: <30°C (86°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glipizide

Pfizer OEL TWA-8 Hr:	0.2 mg/m³

Starch

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for Glipizide. Contact Pfizer Inc for further information.

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:**	White
Odor:	Odorless	**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

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

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

Lactose
Rat Oral LD50 > 10 g/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000 mg/kg

Starch
Mouse IP LD50 6600 mg/kg

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

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

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Stearic acid
Skin Irritation Rabbit Mild

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

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

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

Glipizide
Reproductive & Fertility Rat Oral 50 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 2000 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL No effects at maximum dose
Prenatal & Postnatal Development Rat Oral 50 mg/kg/day NOAEL No effects at maximum dose

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

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

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.

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

Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Stearic acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-313-4

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. 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