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

Product Identifier

Material Name: Glipizide (gastrointestinal therapeutic system (GITS)/Extended Release Tablet)

Trade Name: GLUCOTROL XL; GLIBENESE GITS; MINIDIAB OD; OZIDIA

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antidiabetic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

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:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glipizide</td>
<td>29094-61-9</td>
<td>Not Listed</td>
<td>&lt;5</td>
<td></td>
</tr>
<tr>
<td>Ferric oxide red</td>
<td>1309-37-1</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene oxide NF</td>
<td>25322-68-3</td>
<td>Not Listed</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.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

- **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.

- **Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

5. FIRE FIGHTING MEASURES

- **Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

- **Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

- **Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
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.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Glipizide
Pfizer OEL TWA-8 Hr: 200µg/m³

Ferric oxide red
ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 5 mg/m³
Bulgaria OEL - TWA 5.0 mg/m³
Denmark OEL - TWA 3.5 mg/m³
Estonia OEL - TWA 3.5 mg/m³
Finland OEL - TWA 5 mg/m³
France OEL - TWA 5 mg/m³
Greece OEL - TWA 10 mg/m³
Hungary OEL - TWA 6 mg/m³
SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system (GITS)/Extended Release Tablet)

Revision date: 15-Aug-2018

Version: 4.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

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:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Exposure Control Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs:</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1.5 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Polyethylene oxide NF</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ average molecular weight 200-600</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)</td>
</tr>
<tr>
<td>Pfizer Occupational Exposure Band (OEB):</td>
<td></td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablet
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value)
Ferric oxide red
No data available
Magnesium stearate
No data available
Polyethylene oxide NF
No data available
Sodium chloride
No data available
Hydroxypropyl methylcellulose
No data available
Glipizide
Predicted Log D 0.046
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Antidiabetic drug: has blood-sugar lowering properties
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.

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 LD50 4000 mg/kg

Hydroxypropyl methylcellulose
  Rat Oral LD50 > 10,000 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)

Polyethylene oxide NF
  Eye Irritation Rabbit Mild
  Skin Irritation Rabbit Mild

Sodium chloride
  Eye Irritation Rabbit Moderate
  Skin Irritation Rabbit Mild
11. TOXICOLOGICAL INFORMATION

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. See below

Ferric oxide red
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

Toxicity:

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

Glipizide
- Daphnia magna (Water Flea) 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.

Persistence and Degradability: No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Glipizide

<table>
<thead>
<tr>
<th>Regulation/Standard</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons</td>
<td>Schedule 4</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>249-427-6</td>
</tr>
</tbody>
</table>

Ferric oxide red

<table>
<thead>
<tr>
<th>Regulation/Standard</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-168-2</td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

Sodium chloride
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   EU EINECS/ELINCS List: 231-598-3

Hydroxypropyl methylcellulose
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
   EU EINECS/ELINCS List: Not Listed

Polyethylene oxide NF
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
   EU EINECS/ELINCS List: Not Listed

Magnesium stearate
   CERCLA/SARA 313 Emission reporting: Not Listed
   California Proposition 65: Not Listed
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   EU EINECS/ELINCS List: 209-150-3

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
                  Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 15-Aug-2018

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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