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

Material Name: Chlorpropamide tablets

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Diabinese®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as antidiabetic agent</td>
</tr>
</tbody>
</table>

2. HAZARDS IDENTIFICATION

Appearance: Blue tablets

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

Additional Hazard Information:
- Short Term: Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.
- Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on male reproductive system.

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 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

<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>Chlorpropamide</td>
<td>94-20-2</td>
<td>202-314-5</td>
<td>Not Listed</td>
<td>100 or 250 mg***</td>
</tr>
</tbody>
</table>
3. COMPOSITION/INFORMATION ON 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>471-34-1</td>
<td>207-439-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Alginate acid</td>
<td>9005-32-7</td>
<td>232-680-1</td>
<td>Not Listed</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>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C blue No. 1 lake certified dye</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
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: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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.

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). Wash hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Chlorpropamide
- Pfizer OEL TWA-8 Hr: 1000µg/m³

Calcium carbonate
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Bulgaria OEL - TWA: Listed
- Czech Republic OEL - TWA: Listed
- Estonia OEL - TWA: Listed
- France OEL - TWA: Listed
- Greece OEL - TWA: Listed
- Hungary OEL - TWA: Listed
- Ireland OEL - TWA: Listed
- Latvia OEL - TWA: Listed
- OSHA - Final PELS - TWAs: 15 mg/m³ total
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed

Starch
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Bulgaria OEL - TWA: Listed
- Czech Republic OEL - TWA: Listed
- Greece OEL - TWA: Listed
- Ireland OEL - TWA: Listed
- OSHA - Final PELS - TWAs: 15 mg/m³ total
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed

Magnesium stearate
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Environmental Exposure Controls:
Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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>Color:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet</td>
<td>Blue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Molecular Formula:</th>
<th>Molecular Weight:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Polymerization:
Will not occur

10. STABILITY AND REACTIVITY

Stability:
Stable under normal conditions of use.

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

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)

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 5 g/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Calcium carbonate
Rat  Oral  LD50  6450 mg/kg

Magnesium stearate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 2000 mg/m²

Starch
Mouse  IP  LD50  6600 mg/kg

Chlorpropamide
Rat  Oral  LD50  2150 mg/kg
Mouse  Oral  LD50  1546 mg/kg
Dog  Oral  LD50  800 mg/kg
Rat  Intraperitoneal  LD50  580 mg/kg
Guinea Pig  Oral  LD50  1039 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.

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

Chlorpropamide
67 Week(s)  Rat  Oral  125 mg/kg/day  NOAEL  Male reproductive system
89 Week(s)  Dog  Oral  100 mg/kg/day  NOAEL  None identified
46 Week(s)  Non-human Primate  Oral  200 mg/kg/day  NOAEL  None identified

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

Chlorpropamide
Embryo / Fetal Development  Rat  No route specified  200 mg/day  NOEL  Not teratogenic

Reproductive Effects
Animal reproductive studies have not been conducted with this material. However, rats treated with this material continuously for 6 to 12 months showed varying degrees of suppression of spermatogenesis at higher dosage levels up to 125 mg/kg.

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

Chlorpropamide
Bacterial Mutagenicity (Ames)  Bacteria  Negative
In Vitro  Mouse Lymphoma  Negative
In Vivo  Chromosome Aberration  Human Lymphocytes  Negative
In Vitro  Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Positive
In Vitro  Sister Chromatid Exchange  Human  Positive

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

Chlorpropamide
103-105 Week(s)  Rat  Oral, in feed  6,000 ppm  NOEL  Not carcinogenic
2 Year(s)  Mouse  Oral, in feed  3317 ppm  NOEL  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.

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. 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

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
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.

Chlorpropamide
Australia (AICS): Listed
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List: 202-314-5

Hydroxypropyl cellulose
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed

Calcium carbonate
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Data Sources</th>
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<tr>
<td>Alginic acid</td>
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</tr>
<tr>
<td>Starch</td>
<td>Listed</td>
<td>Listed</td>
<td>232-680-1</td>
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<tr>
<td>Magnesium stearate</td>
<td>Listed</td>
<td>Listed</td>
<td>209-150-3</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. 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 Operations

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End of Safety Data Sheet