MATERIAL SAFETY DATA SHEET

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

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Material Name: Chlorpropamide tablets

Trade Name: Diabinese®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antidiabetic agent

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

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Chlorpropamide	94-20-2	202-314-5	Not Listed	100 or 250 mg***

3. COMPOSITION/INFORMATION ON INGREDIENTS

Calcium carbonate	471-34-1	207-439-9	Not Listed	*
Alginic acid	9005-32-7	232-680-1	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Hydroxypropyl cellulose	9004-64-2	Not listed	Not Listed	*
FD&C blue No. 1 lake certified dye	NOT ASSIGNED	Not listed	Not Listed	*

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/m^3

Calcium carbonate

Australia TWA	10 mg/m^3
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 - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Magnesium stearate

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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. 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

Physical State:	Tablet	**Color:**	Blue
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

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)

Alginic acid
Rat Oral LD50 > 5 g/kg

11. TOXICOLOGICAL INFORMATION

Calcium carbonate
Rat Oral LD50 6450 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

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

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	207-439-9

Alginic acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-680-1

Starch

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

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

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