



SAFETY DATA SHEET

Revision date: 15-Aug-2018

Version: 4.1

Page 1 of 9

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
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New York, New York 10017
1-800-879-3477

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Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

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

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 2 of 9

Version: 4.1

3. COMPOSITION / INFORMATION ON INGREDIENTS

Glipizide	29094-61-9	249-427-6	Not Listed	<5
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Polyethylene oxide NF	25322-68-3	Not Listed	Not Listed	*

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.

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 3 of 9

Version: 4.1

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/m ³
Australia TWA	5 mg/m ³
	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
	10 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Denmark OEL - TWA	3.5 mg/m ³
Estonia OEL - TWA	3.5 mg/m ³
Finland OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
Hungary OEL - TWA	6 mg/m ³

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 4 of 9

Version: 4.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ireland OEL - TWAs	5 mg/m ³ 10 mg/m ³ 4 mg/m ³
Lithuania OEL - TWA	3.5 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³ 15 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 mg/m ³
Russia OEL - TWA	6 mg/m ³
Slovakia OEL - TWA	1.5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3.5 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Sodium chloride	
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Polyethylene oxide NF	
Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL -TWAs	1000 mg/m ³
Magnesium stearate	
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Sodium chloride	
Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³)
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.)

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 5 of 9

Version: 4.1

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	Color:	Blue (2.5 mg) White (5 and 10 mg)
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	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 7.4 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

SAFETY DATA SHEET

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

Revision date: 15-Aug-2018

Page 6 of 9

Version: 4.1

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 > 4000mg/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

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 7 of 9

Version: 4.1

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)	<i>Salmonella</i>	Negative
<i>In Vivo</i> 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

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 8 of 9

Version: 4.1

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Glipizide

Predicted 7.4 Log D 0.046

Mobility in Soil: 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

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	249-427-6

Ferric oxide red

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	215-168-2

SAFETY DATA SHEET

Material Name: Glipizide (gastrointestinal therapeutic system
(GITS)/Extended Release Tablet)
Revision date: 15-Aug-2018

Page 9 of 9

Version: 4.1

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 Schedule 3
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 Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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