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

Product Identifier

Material Name: Miglitol Tablets
Trade Name: Glyset
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

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2

EU Classification:
EU Indication of danger: Toxic to Reproduction: Category 3
EU Risk Phrases:
R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards
Australian Hazard Classification (NOHSC):

No data available

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>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Miglitol</td>
<td>72432-03-2</td>
<td>276-661-6</td>
<td>Repr. Cat.3, R63</td>
<td>Repr. 2, H361d</td>
<td>25-100 mg***</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</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. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

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: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
During all fire fighting 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. Clean up 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.

### Magnesium stearate

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

### Microcrystalline cellulose

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>2 mg/m³</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

### Polyethylene glycol

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ average molecular weight 200-600</td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>1000 ppm</td>
<td></td>
</tr>
</tbody>
</table>

### Starch

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
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</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
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</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

### Titanium dioxide

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>
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).

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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: No data available

Color: White
Odor Threshold: No data available
Molecular Weight: Mixture

Miglitol
Pfizer Occupational Exposure Band (OEB):

OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)
9. PHYSICAL AND CHEMICAL PROPERTIES

pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Miglitol
No data available
Starch
No data available
Microcrystalline cellulose
No data available
Magnesium stearate
No data available
Hydroxypropyl methylcellulose
No data available
Polyethylene glycol
No data available
Titanium dioxide
No data available
Polysorbate 80
No data available
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

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: None known
  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: Not an eye irritant, Not a skin irritant, Not acutely toxic (based on components).
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting.

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

Miglitol
- Rat Oral LD50 > 10,000 mg/kg
- Dog Oral LD50 > 10,000 mg/kg

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

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Hydroxypropyl methylcellulose
- Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 mg/kg

Polysorbate 80
- Rat Oral LD50 25 g/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)

Miglitol
- Eye Irritation Non-irritating
- Skin Irritation Non-irritating

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

Polyethylene glycol
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

Miglitol
- Reproductive & Fertility Rat Oral 300 mg/kg NOAEL Fertility
- Embryo / Fetal Development Rat Oral 150 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity
- Embryo / Fetal Development Rabbit Oral 45 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity
- Peri-/Postnatal Development Rat Oral 100 mg/kg/day NOAEL Fetotoxicity
11. TOXICOLOGICAL INFORMATION

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

Miglitol
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vivo Micronucleus Mouse Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

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

Miglitol
21 Month(s) Mouse Oral 500 mg/kg NOAEL Not carcinogenic
2 Year(s) Rat Oral 500 mg/kg NOAEL Not carcinogenic

Carcinogen Status: See below

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

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

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

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

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

Microcrystalline cellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f]. powder
- EU EINECS/ELINCS List: 232-674-9

Miglitol
- 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: 276-661-6

Polyethylene glycol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
SAFETY DATA SHEET

Material Name: Miglitol Tablets
Revision date: 09-Sep-2014

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Carcinogen initial date 9/2/11 airborne, unbound particles of respirable size</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Toxic to Reproduction: Category 3

R63 - Possible risk of harm to the unborn child.

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

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. New data sheet. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 14 - Transport Information. Updated Section 16 - Other Information.

Revision date: 09-Sep-2014
Prepared by: Product Stewardship Hazard Communication

Pfizer Global Environment, Health, and Safety Operations

PZO0220
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