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

Product Identifier

Material Name: Miglitol
Trade Name: Not established
Chemical Family: Not determined

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

Intended Use: Pharmaceutical active used as antidiabetic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Global Manufacturing
Pfizer Inc
235 East 42nd Street
New York, NY 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
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2

US OSHA Specific - Classification
Physical Hazard: Combustible Dust

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
May form combustible dust concentrations in air

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>Miglitol</td>
<td>72432-03-2</td>
<td>276-661-6</td>
<td>Repr. Cat.3, R63</td>
<td>Repr. 2, H361d</td>
<td>100</td>
</tr>
</tbody>
</table>

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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 Products: Carbon dioxide, carbon monoxide, and oxides of nitrogen

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

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

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
Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s):
Pharmaceutical active

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Miglitol

Pfizer Occupational Exposure Band (OEB):
OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

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

Hands: Wear impervious gloves as minimum protection.
Eyes: Wear safety glasses as minimum protection.
Skin: Wear impervious protective clothing when handling this compound.
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: Powder
Odor: No data available.
Molecular Formula: C8 H17 N O5
Molecular Weight: 207.2
Color: White to pale yellow
Odor Threshold: No data available.

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Soluble: Water
pH: No data available.
pKa: 5.9
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
Miglitol
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: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
10. STABILITY AND REACTIVITY

| Hazardous Decomposition | No data available |

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Short Term: Not an eye irritant, Not a skin irritant, Not acutely toxic (based on animal data).

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

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)

<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; 10,000 mg/kg</td>
</tr>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 10,000 mg/kg</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Non-irritating</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type &amp; Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>300 mg/kg</td>
<td>NOAEL</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>150 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>45 mg/kg/day</td>
<td>NOAEL</td>
</tr>
<tr>
<td>Peri-/Postnatal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>100 mg/kg/day</td>
<td>NOAEL</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type &amp; Species</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella, E. coli</td>
<td>Negative</td>
</tr>
<tr>
<td>In Vivo Micronucleus Mouse</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 Month(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>500 mg/kg</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
<tr>
<td>2 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>500 mg/kg</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
</tbody>
</table>

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation 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

Miglitol

CERCLA/SARA 313 Emission reporting Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>California Proposition 65</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<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>276-661-6</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: 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. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date: 09-Sep-2014

Prepared by: Product Stewardship Hazard Communication

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