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

Material Name: Tolazamide Tablets

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolazamide</td>
<td>1156-19-0</td>
<td>214-588-3</td>
<td>100, 250, 500 mg ***</td>
</tr>
<tr>
<td>Calcium sulfate</td>
<td>7778-18-9</td>
<td>231-900-3</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: *** per tablet/capsule/lozenge/suppository
* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: WARNING

Statement of Hazard: Antidiabetic drug: has blood-sugar lowering properties

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Clinical use of this drug has caused nausea, skin rash, changes in blood cell levels, weakness, fatigue, heartburn, dizziness, decreased blood sugar (hypoglycemia). Clinical use may cause effect on the cardiovascular system.

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.

4. FIRST AID MEASURES

Eye Contact: Flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May burn emitting oxides of: nitrogen, sulfur, carbon.

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tolazamide

Pfizer OEL TWA-8 Hr: 0.1mg/m³
Material Name: Tolazamide Tablets
Revision date: 05-Jan-2007

Analytical Method:
Analytical method available for tolazamide. Contact Pfizer Inc for further information.

Engineering Controls:
Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear impervious gloves if skin contact is possible.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. 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: Tablets
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Polymerization: Will not occur

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)

**Tolazamide**

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>LD 50</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>&gt; 5000</td>
<td>g/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>2239</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>1,000</td>
<td>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.

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

Tolazamide
- 28 Day(s)  Rat  Oral  100 mg/kg/day  NOAEL  None identified
- 34 Day(s)  Dog  Oral  50 mg/kg/day  NOAEL  None identified
- 1 Year(s)  Rat  Oral  25 mg/kg/day  LOEL  Pancreas

Magnesium Stearate
- 13 Week(s)  Rat  Oral  1092 g/kg  LOAEL  Liver

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

Tolazamide
- Reproductive & Fertility  Rat  Oral  <25 mg/kg/day  NOAEL  Fetotoxicity
- Reproductive & Fertility  Rat  Oral  14 mg/kg  NOEL  Fertility, Fetotoxicity
- Embryo / Fetal Development  Rat  Oral  100 mg/kg  LOAEL  Neonatal toxicity, Not Teratogenic

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

Tolazamide
- 103 Week(s)  Rat  Oral, in feed  1000 ppm  NOEL  Not carcinogenic
- 103 Week(s)  Mouse  Oral, in feed  1000 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: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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:
WARNING
Antidiabetic drug: has blood-sugar lowering properties

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.

Tolazamide

Australia (AICS):
Present
Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 4
EU EINECS List
214-588-3

Sodium alginate

Inventory - United States TSCA - Sect. 8(b)
XU
Australia (AICS):
Present

Methylcellulose

Inventory - United States TSCA - Sect. 8(b)
XU
Australia (AICS):
Present

Docusate Sodium

Inventory - United States TSCA - Sect. 8(b)
Present
Australia (AICS):
Present
EU EINECS List
209-406-4

Calcium sulfate

Inventory - United States TSCA - Sect. 8(b)
Present
Australia (AICS):
Present
EU EINECS List
231-900-3

Magnesium Stearate

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

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations.

Prepared by:
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety
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End of Safety Data Sheet