



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

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

**Pfizer Inc**  
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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Tolazamide Tablets

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

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tolazamide	1156-19-0	214-588-3	100, 250, 500 mg ***
Calcium sulfate	7778-18-9	231-900-3	*
Magnesium Stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Sodium alginate	9005-38-3	Not listed	*
Methylcellulose	9004-67-5	Not listed	*
Docusate Sodium	577-11-7	209-406-4	*

**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

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**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/m<sup>3</sup>

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## Calcium sulfate

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

## Magnesium Stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

**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:

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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

Rat	Oral	LD 50	> 5000 g/kg
Mouse	Intraperitoneal	LD 50	2239 mg/kg
Mouse	Intraperitoneal	LD 50	1,000 mg/kg

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**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
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### 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

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## 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**