



# MATERIAL SAFETY DATA SHEET

Revision date: 29-Nov-2007

Version: 1.3

Page 1 of 9

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

**Pfizer Inc**  
**Pfizer Pharmaceuticals Group**  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

**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

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

### Material Name: Triazolam Tablets

<b>Trade Name:</b>	HALCION; Semese
<b>Chemical Family:</b>	Mixture
<b>Intended Use:</b>	Pharmaceutical product used for insomnia.

## 2. HAZARDS IDENTIFICATION

**Appearance:** White, blue tablets.  
**Signal Word:** WARNING

**Statement of Hazard:** Suspected of damaging the unborn child.  
May cause harm to breastfed babies.

**Short Term:** Acute toxicity following ingestion is not expected. Accidental ingestion may cause effects similar to those seen in clinical use.

**Long Term:** Animal studies indicate that this material may cause adverse effects on the heart, liver, lungs, central nervous system.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include fatigue, clumsy motion of limbs/trunk (ataxia), state of intense good feeling (euphoria), incoordination. Other less common effects include hallucinations, delirium, amnesia, addiction, impairment of motor and cognitive skills. The effects are reversible in nature. All observed adverse effects were consistent with the sedative action of this compound. Secreted in human breast milk.

**EU Indication of danger:** Toxic to Reproduction: Category 2

**EU Hazard Symbols:**



**EU Risk Phrases:**

R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.  
Hazardous Substance. Non-Dangerous Goods.

**Australian Hazard Classification (NOHSC):**

# MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 2 of 9  
Version: 1.3

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Triazolam	28911-01-5	249-307-3	R64 Repr. Cat.2;R61	< 77
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Silicon dioxide, NF	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Docusate Sodium	577-11-7	209-406-4	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. 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.

**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.

## 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

# MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 3 of 9  
Version: 1.3

**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:** 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.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

### Triazolam

Pfizer OEL TWA-8 Hr: 0.8µg/m<sup>3</sup>

### Corn Starch

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA  
Belgium OEL - TWA = 10 mg/m<sup>3</sup> TWA  
Bulgaria OEL - TWA = 10.0 mg/m<sup>3</sup> TWA  
Czech Republic OEL - TWA = 4.0 mg/m<sup>3</sup> TWA  
Greece OEL - TWA = 10 mg/m<sup>3</sup> TWA  
Ireland OEL - TWAs = 5 mg/m<sup>3</sup> TWA  
Ireland OEL - TWAs = 10 mg/m<sup>3</sup> TWA  
OSHA - Final PELs - TWAs: = 4 mg/m<sup>3</sup> TWA  
OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
OSHA - Final PELs - TWAs: = 5 mg/m<sup>3</sup> TWA  
Portugal OEL - TWA = 10 mg/m<sup>3</sup> TWA  
Spain OEL - TWA = 10 mg/m<sup>3</sup> VLA-ED

### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA  
Belgium OEL - TWA = 10 mg/m<sup>3</sup> TWA  
Estonia OEL - TWA = 10 mg/m<sup>3</sup> TWA

# MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 4 of 9  
Version: 1.3

France OEL - TWA	= 10 mg/m <sup>3</sup> VME
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA = 4 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA total = 5 mg/m <sup>3</sup> TWA
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Romania OEL - TWA	= 10 mg/m <sup>3</sup> TWA
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED

## 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	
Belgium OEL - TWA	= 10 mg/m <sup>3</sup> TWA	
Ireland OEL - TWAs	= 10 mg/m <sup>3</sup> TWA	except lead stearate
Lithuania OEL - TWA	= 3 mg/m <sup>3</sup> IPRV	
Portugal OEL - TWA	= 10 mg/m <sup>3</sup> TWA	does not include stearates of toxic metals
Spain OEL - TWA	= 10 mg/m <sup>3</sup> VLA-ED	not including stearates of toxic metals
Sweden OEL - TWAs	= 5 mg/m <sup>3</sup> LLV	

## Silicon dioxide, NF

Australia TWA	= 2 mg/m <sup>3</sup> TWA
Austria OEL - MAKs	= 4 mg/m <sup>3</sup> MAK
Czech Republic OEL - TWA	= 0.1 mg/m <sup>3</sup> TWA = 4.0 mg/m <sup>3</sup> TWA
Estonia OEL - TWA	= 2 mg/m <sup>3</sup> TWA
Germany - TRGS 900 - TWAs	= 4 mg/m <sup>3</sup> TWA
Ireland OEL - TWAs	= 2.4 mg/m <sup>3</sup> TWA = 6 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	= 1 mg/m <sup>3</sup> TWA containing more than 70% SiO <sub>2</sub> (quartz) = 2 mg/m <sup>3</sup> TWA containing 10-70% SiO <sub>2</sub> (granite, mica) = 4 mg/m <sup>3</sup> TWA containing 2-10% SiO <sub>2</sub> (copper sulfate ores)
OSHA - Final PELs - Table Z-3 Mineral D:	(80)/(%) SiO <sub>2</sub> mg/m <sup>3</sup> TWA = 20 mppcf TWA
Slovakia OEL - TWA	= 4.0 mg/m <sup>3</sup> TWA
Slovenia OEL - TWA	= 4 mg/m <sup>3</sup> TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

**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:

<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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:

# MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 5 of 9  
Version: 1.3

---

<b>Physical State:</b>	Tablet	<b>Color:</b>	White, blue.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable at normal conditions  
**Conditions to Avoid:** None known  
**Incompatible Materials:** No reactions identified

## 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)

#### Lactose

Rat Oral LD50 > 10 g/kg

#### Sodium benzoate

Rat Oral LD50 4,070 mg/kg  
Mouse Oral LD50 1600 mg/kg

#### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### Triazolam

Rat Oral LD 50 >5000 mg/kg  
Mouse Oral LD 50 > 5,000 mg/kg  
Rat Intraperitoneal LD 50 >5,000 mg/kg  
Mouse Intraperitoneal LD 50 1,625 mg/kg

#### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### Silicon dioxide, NF

Rat Oral LD50 10 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)

#### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### Triazolam

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit No effect

## MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 6 of 9  
Version: 1.3

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

#### **Sodium benzoate**

10 Day(s) Rat Oral 27370 mg/kg LOEL Liver, Blood  
10 Day(s) Mouse Oral 45 g/kg LOEL Liver, Kidney, Blood, Ureter, Bladder

#### **Triazolam**

1 Year(s) Dog Oral 3 mg/kg/day LOEL Central nervous system, Liver  
1 Year(s) Rat Oral 1 mg/kg/day NOAEL Liver, Lungs, Heart  
2 Year(s) Rat Oral 0.5 mg/kg/day NOAEL None identified  
3 Month(s) Dog Oral 100 mg/kg/day LOEL Central Nervous System, Liver  
3 Month(s) Rat Oral 300 mg/kg/day LOEL Central Nervous System

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

#### **Sodium benzoate**

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

#### **Triazolam**

Embryo / Fetal Development Rat Oral 30 mg/kg/day NOAEL Not teratogenic  
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic  
Embryo / Fetal Development Rabbit Oral 5 mg/kg/day LOAEL Not Teratogenic, Fetotoxicity

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

#### **Triazolam**

Bacterial Mutagenicity (Ames) Bacteria Negative  
Direct DNA Damage Not specified Negative

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

#### **Triazolam**

2 Year(s) Mouse Oral, in feed 80 NOAEL Not carcinogenic  
2 Year(s) Rat Oral, in feed 100 NOAEL Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

#### **Silicon dioxide, NF**

**IARC:** Group 3

## **12. ECOLOGICAL INFORMATION**

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

# MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 7 of 9  
Version: 1.3

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Symbol:** T  
**EU Indication of danger:** Toxic to Reproduction: Category 2

**EU Risk Phrases:**  
R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.

**EU Safety Phrases:**  
S36/37 - Wear suitable protective clothing and gloves.  
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
WARNING  
Suspected of damaging the unborn child.  
May cause harm to breastfed babies.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A



### Triazolam

California Proposition 65	developmental toxicity, initial date 4/1/90
Drug Enforcement Administration:	Schedule IV
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	249-307-3

### Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
---	----

# MATERIAL SAFETY DATA SHEET

Material Name: Triazolam Tablets  
Revision date: 29-Nov-2007

Page 8 of 9  
Version: 1.3

<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	232-679-6
<b>Microcrystalline cellulose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	232-674-9
<b>Docusate Sodium</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-406-4
<b>Lactose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	200-559-2
<b>Magnesium stearate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3
<b>Silicon dioxide, NF</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	231-545-4 EEC No. 418-260-2
<b>Sodium benzoate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	208-534-8

**Additional Information:** US DEA Schedule IV substance

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

**Data Sources:** Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety



## MATERIAL SAFETY DATA SHEET

**Material Name: Triazolam Tablets**  
**Revision date: 29-Nov-2007**

**Page 9 of 9**  
**Version: 1.3**

---

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**