



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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## 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

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

### Material Name: Ketazolam Capsules

Trade Name: Marcen  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as antianxiety agent.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ketazolam	27223-35-4	248-346-3	15mg;30mg;45mg***

Ingredient	CAS Number	EU EINECS List	%
Hydrogenated vegetable oil	68334-00-9	269-804-9	*
Carboxy methylcellulose calcium	9050-04-8	Not listed	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** White capsules  
**Signal Word:** WARNING

**Statement of Hazard:** Anti-anxiety drug: causes central nervous system effects

### Additional Hazard Information:

**Short Term:** Not acutely toxic : Not expected to cause skin irritation , eye irritation (based on components) .  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, spleen, kidneys and bone marrow

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include drowsiness, lightheadedness and headache. The following effects are based on a chemically-related material: symptoms of dependence/withdrawal. May cause adverse effects on the developing fetus.

**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 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.

### 5. FIRE FIGHTING MEASURES

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

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

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not determined

### 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

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**General Handling:** Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Ketazolam

**Pfizer OEL TWA-8 Hr:** 15ug/m<sup>3</sup>  
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:** Analytical method available for Ketazolam. 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 protective gloves when working with large quantities.

**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>	Capsule	<b>Color:</b>	White
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None for the normal use of this material

**Incompatible Materials:** No reactions identified

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the active ingredient.

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

#### Ketazolam

Rat	Oral	LD 50	5 g/kg
Mouse	Oral	LD 50	2 g/kg
Rat	Intraperitoneal	LD 50	3.9 g/kg
Mouse	Intraperitoneal	LD 50	2.6 g/kg

#### Irritation / Sensitization: (Study Type, Species, Severity)

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### Ketazolam

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit No effect

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

#### Ketazolam

92 Day(s)	Mouse	Oral	30 mg/kg/day	NOAEL	Liver
95 Day(s)	Rat	Oral	10 mg/kg/day	NOAEL	Adrenal gland, Kidney, Liver
1 Year(s)	Rat	Oral	10 mg/kg/day	NOAEL	Central Nervous System, Kidney, Liver, Bone Marrow, Spleen
28 Week(s)	Dog	Oral	6 mg/kg/day	NOAEL	Central Nervous System
1 Year(s)	Dog	Oral	1 mg/kg/day	NOAEL	Kidney

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

#### Ketazolam

Reproductive & Fertility	Rat	Oral	20 mg/kg/day	NOAEL	No effects at maximum dose
Peri-/Postnatal Development	Rat	Oral	10 mg/kg/day	NOAEL	Fetotoxicity
Embryo / Fetal Development	Mouse	Oral	100 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	10 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	100 mg/kg/day	NOAEL	Not Teratogenic

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

#### Ketazolam

*In Vivo* Micronucleus Rat Negative  
Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

#### Ketazolam

2 Year(s)	Mouse	Oral	50	NOAEL	Not carcinogenic
22 Month(s)	Rat	Oral	100	NOAEL	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 thoroughly 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.

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## 15. REGULATORY INFORMATION

EU Indication of danger: Not classified

### OSHA Label:

WARNING

Anti-anxiety drug: causes central nervous system effects

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

D2b toxic materials



#### Ketazolam

California Proposition 65	developmental toxicity, initial date 10/1/92
Drug Enforcement Administration:	Schedule IV
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	248-346-3

#### Hydrogenated vegetable oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	269-804-9

#### Carboxy methylcellulose calcium

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

Additional Information: US DEA Schedule IV substance

## 16. OTHER INFORMATION

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet