



# MATERIAL SAFETY DATA SHEET

Revision date: 09-Apr-2007

Version: 1.0

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

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### Material Name: Oxazepam Tablets

**Trade Name:** Sobril®  
**Compound Number:** PNU-0029556  
**Chemical Family:** Benzodiazepine  
**Intended Use:** Pharmaceutical product used as antianxiety agent.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Oxazepam	604-75-1	210-076-9	6-28
Magnesium Stearate	557-04-0	209-150-3	*
Microcrystalline cellulose	9004-34-6	232-674-9	*

Ingredient	CAS Number	EU EINECS List	%
Dibasic calcium phosphate, dihydrate USP	7789-77-7	Not listed	*
Povidone	9003-39-8	Not listed	*
Silica colloidal, Ph. Eur.	112945-52-5	Not listed	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Sodium starch glycolate	9063-38-1	Not listed	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Round, white tablet

**Statement of Hazard:** Suspected of causing cancer.  
Suspected of damaging fertility or the unborn child.  
May cause damage to gastrointestinal system and central nervous system through prolonged or repeated exposure.

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**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include drowsiness and lethargy Other less common effects include dizziness vertigo headache fainting (syncope) Drugs of this class may cause symptoms of dependence/withdrawal This material has been shown to be secreted in low concentrations in human breast milk. This compound can cross the placenta in pregnant women.

**EU Indication of danger:** Carcinogenic: Category 3  
Toxic to Reproduction; Category 3

**EU Hazard Symbols:**



**EU Risk Phrases:** R40 - Limited evidence of a carcinogenic effect  
R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

**Australian Hazard Classification (NOHSC):**

**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:** No data available

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

**Fire / Explosion Hazards:** No data available

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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**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 at controlled room temperature.

**Storage Temperature:** < 25 °C

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

**Microcrystalline cellulose**  
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

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.

**Oxazepam**  
Pfizer Occupational Exposure Band (OEB): OEB4 (control exposure to the range of >1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

**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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

### Personal Protective Equipment:

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

## 10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.  
Conditions to Avoid: No data available  
Incompatible Materials: No data available

## 11. TOXICOLOGICAL INFORMATION

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

#### Oxazepam

Rat	Oral	LD50	>8 g/kg
Mouse	Oral	LD50	1540 mg/kg
Rabbit	Oral	LD50	>2 g/kg
Rat	Subcutaneous	LD50	>8 g/kg
Mouse	Subcutaneous	LD50	>400 mg/kg

#### Sodium Lauryl Sulfate

Rat	Oral	LD 50	1288 mg/kg
Rat	Intraperitoneal	LD 50	210 mg/kg

#### Microcrystalline cellulose

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

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

#### Oxazepam

2 Year(s)	Rat	Oral	25 mg/kg	NOAEL	Kidney, Liver, Gastrointestinal System
14 Week(s)	Mouse	Oral	25 mg/kg	LOAEL	Central Nervous System, Liver
52 Week(s)	Dog	Oral	10,920 mg/kg/day	LOAEL	Endocrine system
6 Week(s)	Rat	Oral	5,250 mg/kg/day	LOAEL	Bladder, Endocrine system

#### Sodium Lauryl Sulfate

3 Day(s)	Rat	Oral	75 mg/kg	LOAEL	Liver, Blood
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#### 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))

#### **Oxazepam**

Reproductive & Fertility	Rat	Oral	100 mg/kg/day	NOAEL	No effects at maximum dose, Not teratogenic
Reproductive & Fertility	Mouse	Oral	500 mg/kg/day	LOAEL	Reproductive toxicity
Embryo / Fetal Development	Mouse	Feeding tube	375 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	Oral	50 mg/kg	NOAEL	Not Teratogenic
Fertility and Embryonic Development	Mouse	Oral	400 mg/kg	LOAEL	Fetotoxicity, Not Teratogenic

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

#### **Oxazepam**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Human Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative

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

#### **Oxazepam**

2 Year(s)	Rat	Oral, in feed	25 mg/kg/day	LOAEL	Kidneys, Tumors, Equivocal
2 Year(s)	Rat	Oral, in feed	220 mg/kg/day	NOAEL	Not carcinogenic
57 Week(s)	Mouse	Oral, in feed	270 mg/kg/day	LOAEL	Liver, Tumors
2 Year(s)	Mouse	Oral, in feed	12 mg/kg/day	LOAEL	Liver, Tumors

**Carcinogen Status:** See below

#### **Oxazepam**

**IARC:** Group 2B

**OSHA:** Present

#### **Silica colloidal, Ph. Eur.**

**IARC:** Group 3

#### **Povidone**

**IARC:** Group 3

## 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.

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## 14. TRANSPORT INFORMATION

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

## 15. REGULATORY INFORMATION

**EU Symbol:** Xn  
**EU Indication of danger:** Carcinogenic: Category 3  
Toxic to Reproduction; Category 3

**EU Risk Phrases:**  
R40 - Limited evidence of a carcinogenic effect  
R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.

**EU Safety Phrases:**  
S36/37 - Wear suitable protective clothing and gloves.

**OSHA Label:**  
Suspected of causing cancer.  
Suspected of damaging fertility or the unborn child.  
May cause damage to gastrointestinal system and central nervous system through prolonged or repeated exposure.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
D2b toxic materials  
D2a very toxic materials



### **Oxazepam**

<b>California Proposition 65</b>	carcinogen, initial date 10/01/94 developmental toxicity, initial date 10/1/92
<b>Drug Enforcement Administration:</b>	Schedule IV
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS List</b>	210-076-9

<b>Dibasic calcium phosphate, dihydrate USP</b>	
<b>Australia (AICS):</b>	Present

**Magnesium Stearate**

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<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	209-150-3
<b>Microcrystalline cellulose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	232-674-9
<b>Povidone</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>Silica colloidal, Ph. Eur.</b>	
<b>Australia (AICS):</b>	Present
<b>Sodium Lauryl Sulfate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	205-788-1
<b>Sodium starch glycolate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present

## 16. OTHER INFORMATION

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

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.

**End of Safety Data Sheet**