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

Material Name: Oxazepam Tablets

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxazepam</td>
<td>604-75-1</td>
<td>210-076-9</td>
<td>6-28</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
</tbody>
</table>

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

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.
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.

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.
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/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Microcrystalline cellulose
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ 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/m³ to <10ug/m³)

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.
9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
<th>Color: White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight: Mixture</td>
</tr>
</tbody>
</table>

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 LD50 1288 mg/kg
- Rat Intrapertoneal 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

Magnesium Stearate
- 13 Week(s) Rat Oral 1092 g/kg LOAEL Liver
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
- **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)** *Salmonella* Negative
- **In Vitro** Sister Chromatid Exchange Human Chinese Hamster Ovary (CHO) cells Negative
- **In Vitro** Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
- **In Vivo** 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.
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
California Proposition 65
carcinogen, initial date 10/01/94
developmental toxicity, initial date 10/1/92

Drug Enforcement Administration:
Schedule IV

Australia (AICS):
Present

Standard for the Uniform Scheduling for Drugs and Poisons:
Schedule 4

EU EINECS List
210-076-9

Dibasic calcium phosphate, dihydrate USP
Australia (AICS):
Present

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

**Microcrystalline cellulose**

Inventory - United States TSCA - Sect. 8(b)        XU
Australia (AICS):                                Present
EU EINECS List                                  232-674-9

**Povidone**

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

**Silica colloidal, Ph. Eur.**

Australia (AICS):                                Present

**Sodium Lauryl Sulfate**

Inventory - United States TSCA - Sect. 8(b)        Present
Australia (AICS):                                Present
EU EINECS List                                  205-788-1

**Sodium starch glycolate**

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

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**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**