MATERIAL SAFETY DATA SHEET

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

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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Alprazolam Tablets

Trade Name: XANAX®; RALOZAM; XANOR; FRONTAL; ZOTRAN; TAFIL
Chemical Family: Benzodiazepine
Intended Use: Pharmaceutical product used as antianxiety agent

2. HAZARDS IDENTIFICATION

Appearance: White, peach, or blue tablets
Signal Word: WARNING

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

Additional Hazard Information:

Short Term: Active ingredient may be harmful if swallowed. May cause eye irritation if tablets are crushed or broken.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on central nervous system.

Known Clinical Effects: Common adverse effects include dizziness and drowsiness, lightheadedness, dry mouth, and symptoms of dependence/withdrawal.

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.


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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>28981-97-7</td>
<td>249-349-2</td>
<td>0.2-0.8</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Docusate Sodium</td>
<td>577-11-7</td>
<td>209-406-4</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>*</td>
</tr>
</tbody>
</table>

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

4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May include oxides of carbon.

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

Fire / Explosion Hazards: Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

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 room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Alprazolam
Pfizer OEL TWA-8 Hr: 3 µg/m³

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

Corn Starch
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

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

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


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:

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: 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:

Physical State: Tablets
Molecular Formula: Mixture
Color: White, peach, or blue
Molecular Weight: Mixture
10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

Alprazolam
- Rat Oral LD 50 1220 (F) mg/kg
- Rat Oral LD 50 3100 (M) mg/kg
- Mouse Oral LD 50 1410-1700 mg/kg
- Rat Intravenous LD 50 ~ 15 mg/kg

Lactose
- Rat Oral LD50 > 10 g/kg

Sodium benzoate
- Rat Oral LD50 4,070 mg/kg
- Mouse Oral LD50 1600 mg/kg

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

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)

Alprazolam
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Non-irritating

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

Alprazolam
- 1 Year(s) Dog Oral 3-30 mg/kg LOAEL Central nervous system
- 1 Year(s) Rat Oral 25 mg/kg/day NOAEL None identified
- 2 Year(s) Rat Oral 3, 10, 30 mg/kg/day Eyes

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

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

Alprazolam
- Reproductive & Fertility Rat Oral 5 mg/kg/day NOAEL Negative
- Embryo / Fetal Development Rat Oral 5 mg/kg/day NOAEL Embryotoxicity
- Embryo / Fetal Development Rabbit Oral 0.5 mg/kg/day NOAEL Embryotoxicity, Teratogenic
Material Name: Alprazolam Tablets
Revision date: 21-May-2007

11. TOXICOLOGICAL INFORMATION

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

Alprazolam
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vivo Micronucleus  Rat  Negative
Direct DNA Interaction  Salmonella  Negative

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

Alprazolam
2 Year(s)  Rat  Oral  30 mg/kg/day  Not carcinogenic
104 Week(s)  Mouse  Oral  10 mg/kg/day  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.

15. REGULATORY INFORMATION

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:
S22 - Do not breathe dust.
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 1, Subdivision A

Alprazolam
California Proposition 65: developmental toxicity, initial date 7/1/90
Drug Enforcement Administration: Schedule IV
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List: 249-349-2

Lactose
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-559-2

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

Docusate Sodium
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 209-406-4

Sodium benzoate
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 208-534-8

Corn Starch
Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present
EU EINECS/ELINCS List: 232-679-6

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 209-150-3
16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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