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

**Product Identifier**

**Material Name:** Alprazolam Tablets

**Trade Name:** XANAX; RALOZAM; XANOR; FRONTAL; ZOTRAN; TAFIL

**Chemical Family:** Benzodiazepine

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**

**Intended Use:** Pharmaceutical product used as an antianxiety agent

**Details of the Supplier of the Safety Data Sheet**

**Pfizer Inc**
- Pfizer Pharmaceuticals Group
- 235 East 42nd Street
- New York, New York 10017
- 1-800-879-3477

**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
- International CHEMTREC (24 hours): +1-703-527-3887

**Contact E-Mail:** pfizer-MSDS@pfizer.com

### 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification**

- Reproductive Toxicity: Category 2
- Effects on or via lactation

**EU Classification:**

- 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.

**Label Elements**

- **Signal Word:** Warning
- **Hazard Statements:**
  - H361d - Suspected of damaging the unborn child

- **Precautionary Statements:**
  - P201 - Obtain special instructions before use
  - P202 - Do not handle until all safety precautions have been read and understood
  - P281 - Use personal protective equipment as required
  - P308 + P313 - IF exposed or concerned: Get medical attention/advice
  - P405 - Store locked up
  - P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Alprazolam Tablets
Revision date: 07-Jul-2014

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>28981-97-7</td>
<td>249-349-2</td>
<td>Xn;R22</td>
<td>Repr.Cat.2;R61</td>
<td>0.2-0.8</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docusate Sodium</td>
<td>577-11-7</td>
<td>209-406-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>532-32-1</td>
<td>208-534-8</td>
<td>Not Listed</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.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe 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. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

Microcrystalline cellulose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³

Corn Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Exposure Controls
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: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

- **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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical State:</strong></td>
<td>Tablets</td>
</tr>
<tr>
<td><strong>Odor:</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Molecular Formula:</strong></td>
<td>Mixture</td>
</tr>
<tr>
<td><strong>Solvent Solubility:</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Water Solubility:</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>pH:</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Melting/Freezing Point (°C):</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Boiling Point (°C):</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Partition Coefficient:</strong></td>
<td>No data available.</td>
</tr>
</tbody>
</table>

**Alprazolam**

- Predicted $\log D = 2.50$

**Lactose**

- No data available

**Docusate Sodium**

- No data available

**Sodium benzoate**

- No data available

**Corn Starch**

- No data available

**Magnesium stearate**

- No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

- **Reactivity:** No data available
- **Chemical Stability:** Stable at normal conditions
- **Possibility of Hazardous Reactions**
  - **Oxidizing Properties:** No data available
## 10. STABILITY AND REACTIVITY

**Conditions to Avoid:**
Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:**
As a precautionary measure, keep away from strong oxidizers.

**Hazardous Decomposition Products:**
No data available

## 11. TOXICOLOGICAL INFORMATION

### General Information:
The information included in this section describes the potential hazards of the individual ingredients.

### 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 the central nervous system.

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

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>1220 (F) mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>3100 (M)mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>1410-1700mg/kg</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>1600mg/kg</td>
</tr>
</tbody>
</table>

### 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)

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Skin Irritation</td>
<td>Rabbit</td>
<td>Non-irritating</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>1 Year(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>3-30 mg/kg</td>
<td>LOAEL</td>
<td>Central nervous system</td>
</tr>
<tr>
<td></td>
<td>1 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>NOAEL</td>
<td>None identified</td>
</tr>
<tr>
<td></td>
<td>2 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>3, 10, 30 mg/kg/day</td>
<td>Eyes</td>
<td>Eyes</td>
</tr>
<tr>
<td>Sodium benzoate</td>
<td>10 Day(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>27370 mg/kg</td>
<td>LOAEL</td>
<td>Liver, Blood</td>
</tr>
<tr>
<td></td>
<td>10 Day(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>45 g/kg</td>
<td>LOAEL</td>
<td>Liver, Kidney, Blood, Ureter, Bladder</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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

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

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.

Toxicity:
No data available

Persistence and Degradability:
No data available

Bio-accumulative Potential:
No data available

Partition Coefficient: (Method, pH, Endpoint, Value)
Alprazolam
Predicted 7.4 Log D 2.50

Mobility in Soil:
No data available
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision A

Alprazolam
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: developmental toxicity initial date 7/1/90
U.S. Drug Enforcement Administration: Schedule IV Controlled Substance
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List: 249-349-2

Microcrystalline cellulose
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List: 232-674-9

Docusate Sodium
15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-406-4

Corn Starch
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 232-679-6

Magnesium stearate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Lactose
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 200-559-2

Sodium benzoate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 208-534-8

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
Xn - Harmful
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

ALPRAZOLAM TABLETS
SAFETY DATA SHEET

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date: 07-Jul-2014
Prepared by: Product Stewardship Hazard Communication

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