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

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

Material Name: Alprazolam Drops

Trade Name: XANAX®
Chemical Family: Benzodiazepine
Intended Use: Pharmaceutical product used as an antianxiety agent

2. HAZARDS IDENTIFICATION

Appearance: A yellow liquid with an alcohol odor

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: May cause eye irritation (based on components). Active ingredient may be harmful if swallowed. Ingestion of large quantities may cause may cause headache, dizziness, nausea, vomiting, diarrhea, drowsiness, and symptoms of drunkenness. Inhalation of the vapors may cause irritation of the upper respiratory passages, possibly with coughing and discomfort; temporary nervous system depression with anesthetic effects such as dizziness, headache, confusion, incoordination, and loss of consciousness; abnormal liver function as detected by laboratory test; or nonspecific discomfort, such as nausea, headache, or weakness.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on nervous system and fetus. Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations.

Known Clinical Effects: Common adverse effects include lightheadedness, dizziness and drowsiness, and dry mouth.

EU Indication of danger: Not classified

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F;R11</td>
<td>12</td>
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<tr>
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<td>249-349-2</td>
<td>R64</td>
<td>0.07</td>
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<td></td>
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<tr>
<td>Additional Information:</td>
<td>* Proprietary</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grapefruit Flavor</td>
<td>Not Assigned</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
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<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium saccharin USP</td>
<td>128-44-9</td>
<td>204-886-1</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.

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Dry chemical, carbon dioxide, water spray or alcohol-resistant foam

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: May generate flammable vapors. 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 spill with absorbent material. 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: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ethanol

ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA
Australia TWA = 1000 ppm TWA
= 1880 mg/m³ TWA
Austria OEL - MAKs = 1000 ppm MAK
= 1900 mg/m³ MAK
Belgium OEL - TWA = 1000 ppm TWA
= 1907 mg/m³ TWA
Bulgaria OEL - TWA = 1000.0 mg/m³ TWA
Czech Republic OEL - TWA = 1000 mg/m³ TWA
Denmark OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
Estonia OEL - TWA = 1000 mg/m³ TWA
= 500 ppm TWA
Finland OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
France OEL - TWA = 1000 ppm VME
= 1900 mg/m³ VME
Germany - TRGS 900 - TWAs = 500 ppm TWA
= 960 mg/m³ TWA
Greece OEL - TWA = 1000 ppm TWA
= 1900 mg/m³ TWA
Hungary OEL - TWA = 1900 mg/m³ TWA
Ireland OEL - TWAs = 1000 ppm TWA
= 1900 mg/m³ TWA
Latvia OEL - TWA = 1000 mg/m³ TWA
Lithuania OEL - TWA = 1000 mg/m³ IPRV
= 500 ppm IPRV
Netherlands OEL - TWA = 1000 mg/m³ MAC
= 500 ppm MAC
Analytical Method:
Analytical method available for Alprazolam. Contact Pfizer Inc for further information.

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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Alcoholic</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

Color: Golden - Yellow
Molecular Formula: Mixture
### 10. STABILITY AND REACTIVITY

**Stability:** Stable at normal conditions  
**Conditions to Avoid:** Heat, sparks, flame, and electrostatic discharge  
**Incompatible Materials:** Acids, bases, and 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

**Ethanol**
- Mouse Oral LD50 3,450 g/m³  
- Rat Oral LD50 7,060 mg/kg  
- Mouse Inhalation LC50 4h 39 g/m³  
- Rat Inhalation LC50 10h 20,000 ppm

**Propylene glycol**
- Mouse Oral LD50 22,000 mg/kg  
- Rat Oral LD50 20,000 mg/kg  
- Rabbit Dermal LD50 20,800 mg/kg

**Sodium saccharin USP**
- Mouse Oral LD50 17.5 g/kg  
- Rat Oral LD50 14.2 - 17 g/kg

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

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

**Ethanol**
- Eye Irritation Rabbit Severe

**Propylene glycol**
- Skin Irritation Rabbit Mild  
- Eye Irritation Rabbit Mild

#### 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
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

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. See below

Sodium saccharin USP
IARC:  Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethanol
Fingerling Trout  NPDES  LC50  24 Hours  11,200 mg/L
Rainbow Trout  NPDES  LC50  96 Hours  12,900 mg/L
Fathead minnow  NPDES  LC50  96 Hours  14,200 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Ethanol

California Proposition 65: developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-578-6

Propylene glycol

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-338-0

Water, purified

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: 231-791-2

Sodium saccharin USP

Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 204-886-1

ALPRAZOLAM DROPS
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 8 - Exposure Controls / Personal Protection.

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet