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

Product Identifier

Material Name: Alprazolam XR Tablets
Trade Name: XANAX XR; XANOR SR; TAFIL SR
Synonyms: Alprazolam Extended Release Tablets
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antianxiety agent

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

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

Label Elements

Signal Word: Warning
Hazard Statements: H361d - Suspected of damaging the unborn child
H362 - May cause harm to breast-fed children

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 XR Tablets
Revision date: 06-Mar-2019

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>28981-97-7</td>
<td>249-349-2</td>
<td>Acute Tox.4 (H302) Repr.1B (H360D) Lact.(H362)</td>
<td>0.1-0.9</td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</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>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>FD&amp;C Blue No. 2</td>
<td>860-22-0</td>
<td>212-728-8</td>
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<td>*</td>
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<tr>
<td>D &amp; C yellow No. 10</td>
<td>8004-92-0</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxymethylcellulose</td>
<td>9004-65-3</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 CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed
- Symptoms and Effects of Exposure: No data available
- 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: May include oxides of carbon.
- Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters
- During all firefighting 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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
- If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Use appropriate ventilation. 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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.
- Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Alprazolam

Pfizer OEL TWA-8 Hr: 3 µg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
                      4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
                      2.4 mg/m³
Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
                      Listed
Slovakia OEL - TWA 4.0 mg/m³
Slovenia OEL - TWA 0.3 mg/m³
Switzerland OEL - TWAs 4 mg/m³

Magnesium stearate

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>White Yellow Blue or Green</th>
</tr>
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<tbody>
<tr>
<td>Odor:</td>
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<tr>
<td>Molecular Formula:</td>
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<td>Molecular Weight:</td>
<td>Mixture</td>
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<tr>
<td>Boiling Point (°C):</td>
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<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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Alprazolam
Predicted 7.4 Log D 2.50
FD&C Blue No. 2
No data available
D & C yellow No. 10
No data available
Silicon dioxide, NF
No data available
Lactose
No data available
Hydroxypropyl methylcellulose
No data available
Magnesium stearate
No data available

<table>
<thead>
<tr>
<th>Decomposition Temperature (°C):</th>
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<tr>
<td>Evaporation Rate (Gram/s):</td>
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<tr>
<td>Vapor Pressure (kPa):</td>
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<td>Vapor Density (g/ml):</td>
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<tr>
<td>Relative Density:</td>
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<tr>
<td>Viscosity:</td>
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<table>
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<tbody>
<tr>
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<td>Flammability (Solids):</td>
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<td></td>
<td>Flash Point (Liquid) (°C):</td>
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<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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<td></td>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
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<tr>
<td>Polymerization:</td>
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10. STABILITY AND REACTIVITY

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<th>Reactivity:</th>
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<tr>
<td>Chemical Stability:</td>
<td>Stable under normal conditions of use.</td>
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<tr>
<td>Possibility of Hazardous Reactions</td>
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<tr>
<td>Oxidizing Properties:</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid:</td>
<td>Fine particles (such as dust and mist) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials:</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products:</td>
<td>No data available</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Short Term: Not expected to cause skin irritation. Active ingredient may be harmful if swallowed.

Long Term: Animal studies indicate that this material may cause adverse effects on the nervous system, the developing fetus.

Known Clinical Effects: The most common adverse effects observed with the clinical use of this drug were headache, nausea, and somnolence.

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

Alprazolam
- Rat Oral LD50 1220 (F) mg/kg
- Rat Oral LD50 3100 (M) mg/kg
- Mouse Oral LD50 1410-1700 mg/kg
- Rat Intravenous LD50 ~ 15 mg/kg

FD&C Blue No. 2
- Rat Oral LD50 2 g/kg
- Mouse Oral LD50 2500 mg/kg

D & C yellow No. 10
- Rat Oral LD50 2000 mg/kg

Hydroxypropyl methylcellulose
- Rat Oral LD50 > 10,000 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

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
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

FD&C Blue No. 2
Bacterial Mutagenicity (Ames) 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: See below

Silicon dioxide, NF
IARC: Group 3 (Not Classifiable)
NTP: Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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

Alprazolam
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: developmental toxicity 7/1/1990
- U.S. Drug Enforcement Administration: Schedule IV Controlled Substance
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 8
- EU EINECS/ELINCS List: 249-349-2

FD&C Blue No. 2
- 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: 212-728-8

D & C yellow No. 10
- 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: Not Listed

Silicon dioxide, NF
- 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: 231-545-4

Lactose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
SAFETY DATA SHEET

Material Name: Alprazolam XR Tablets
Revision date: 06-Mar-2019

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Present</td>
<td>200-559-2</td>
</tr>
</tbody>
</table>

Hydroxypropyl methylcellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

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

16. OTHER INFORMATION

Text of CLP/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

Data Sources:
Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision:
- Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information.
- Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Revision date: 06-Mar-2019
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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

PZ01153