



MATERIAL SAFETY DATA SHEET

Revision date: 07-Apr-2010

Version: 1.3

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Alprazolam XR Tablets

Trade Name:	XANAX XR; XANOR SR; TAFIL SR
Synonyms:	Alprazolam Extended Release Tablets
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antianxiety agent

2. HAZARDS IDENTIFICATION

Appearance: White green blue or yellow tablets
Signal Word: WARNING

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

Additional Hazard Information:

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.

EU Classification

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Alprazolam	28981-97-7	249-349-2	R64 Repr.Cat.2;R61 Xn;R22	0.1-0.9
Silicon dioxide, NF	7631-86-9	231-545-4	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
FD&C Blue No. 2	860-22-0	212-728-8	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not listed	Not Listed	*
D & C yellow No. 10	8004-92-0	Not listed	Not Listed	*
Lactose	63-42-3	200-559-2	Not Listed	*

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.

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:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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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:	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.
Storage Conditions:	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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/m ³
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³ MAK
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(%) SiO ₂ mg/m ³ TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

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

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.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear protective gloves when working with large quantities.

Eyes: Wear safety glasses or goggles if eye contact is possible. Not required under normal conditions of use.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: None required 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	White Yellow Blue or Green
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Polymerization:	Will not occur		

10. STABILITY AND REACTIVITY

Chemical 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

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
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Silicon dioxide, NF

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11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 10 g/kg

Lactose

Rat Oral LD50 > 10 g/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

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:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
See below

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11. TOXICOLOGICAL INFORMATION

Silicon dioxide, NF

IARC:

Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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

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

15. REGULATORY INFORMATION

EU Symbol:

T

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:

S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

WARNING

May cause harm to the unborn child.

May cause harm to breastfed babies.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision A

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15. REGULATORY INFORMATION



Alprazolam

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

FD&C Blue No. 2

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	212-728-8

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4

Hydroxypropyl methylcellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

D & C yellow No. 10

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

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

Lactose

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

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Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet