



MATERIAL SAFETY DATA SHEET

Revision date: 21-May-2007

Version: 1.0

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

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Emergency telephone number:
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.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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	%
Alprazolam	28981-97-7	249-349-2	0.2-0.8
Corn Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*

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

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.

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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.

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:

Physical State:	Tablets	Color:	White, peach, or blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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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

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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.

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.

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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

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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