



MATERIAL SAFETY DATA SHEET

Revision date: 30-Jul-2007

Version: 1.2

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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 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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Ethanol	64-17-5	200-578-6	F;R11	12
Alprazolam	28981-97-7	249-349-2	R64 Repr.Cat.2;R61 Xn;R22	0.07

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

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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/m ³ TWA
Austria OEL - MAKs	= 1000 ppm MAK
	= 1900 mg/m ³ MAK
Belgium OEL - TWA	= 1000 ppm TWA
	= 1907 mg/m ³ TWA
Bulgaria OEL - TWA	= 1000.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 1000 mg/m ³ TWA
Denmark OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Estonia OEL - TWA	= 1000 mg/m ³ TWA
	= 500 ppm TWA
Finland OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
France OEL - TWA	= 1000 ppm VME
	= 1900 mg/m ³ VME
Germany - TRGS 900 - TWAs	= 500 ppm TWA
	= 960 mg/m ³ TWA
Greece OEL - TWA	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Hungary OEL - TWA	= 1900 mg/m ³ TWA
Ireland OEL - TWAs	= 1000 ppm TWA
	= 1900 mg/m ³ TWA
Latvia OEL - TWA	= 1000 mg/m ³ TWA
Lithuania OEL - TWA	= 1000 mg/m ³ IPRV
	= 500 ppm IPRV
Netherlands OEL - TWA	= 1000 mg/m ³ MAC
	= 500 ppm MAC

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OSHA - Final PELs - TWAs:	= 1000 ppm TWA = 1900 mg/m ³ TWA
Poland OEL - TWA	= 1900 mg/m ³ NDS
Portugal OEL - TWA	= 1000 ppm TWA
Romania OEL - TWA	= 1000 ppm TWA = 1900 mg/m ³ TWA
Slovakia OEL - TWA	= 500 ppm TWA = 960 mg/m ³ TWA
Slovenia OEL - TWA	= 1000 ppm TWA = 1900 mg/m ³ TWA
Spain OEL - TWA	= 1000 ppm VLA-ED = 1910 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 1000 mg/m ³ LLV = 500 ppm LLV

Propylene glycol	
Australia TWA	= 10 mg/m ³ TWA = 150 ppm TWA = 474 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA = 150 ppm TWA = 470 mg/m ³ TWA
Latvia OEL - TWA	= 7 mg/m ³ TWA
Lithuania OEL - TWA	= 7 mg/m ³ IPRV

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

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:	Solution	Color:	Golden - Yellow
Odor:	Alcoholic	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

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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

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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)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative
Direct DNA Interaction	<i>Salmonella</i>	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.

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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

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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

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