



MATERIAL SAFETY DATA SHEET

Revision date: 01-Sep-2009

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Diazepam Injectable Emulsion

Trade Name: Diazemuls
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antianxiety agent

2. HAZARDS IDENTIFICATION

Appearance: Liquid

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

Short Term: Harmful if swallowed (based on animal data) .
Long Term: Use of this drug is habit forming. Addiction may occur. Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Therapeutic use of this substance has resulted in weakness, dizziness, drowsiness, ataxia, confusion, tremors, headache, and gastrointestinal disturbances.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Diazepam	439-14-5	207-122-5	Xn;R22 Repr.Cat.3;R63-64	0.5
Glycerol	56-81-5	200-289-5	Not Listed	*
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Fractionated Soya Oil	Not assigned	Not listed	Not Listed	*
Acetylated monoglycerides	Not assigned	Not listed	Not Listed	*
Fractionated egg lecithin	Not assigned	Not listed	Not Listed	*

Additional Information:

* Proprietary

** to adjust pH

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 with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	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.

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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:

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation.

Storage Conditions:

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

Storage Temperature:

15 - 25°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Diazepam

Pfizer OEL TWA-8 Hr:	7µg/m ³
Bulgaria OEL - TWA	Listed

Glycerol

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	50 mg/m ³ MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m ³
Australia PEAK	2 mg/m ³
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Japan - OELs - Ceilings	2 mg/m ³
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	2 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Analytical Method:	Analytical method available for Diezepam. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system.
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 impervious gloves if skin contact is possible.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
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:	Liquid	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
pH:	8		

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information:	There are no data for this formulation. The remaining information describes the potential hazards of the individual ingredients.
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Acute Toxicity: (Species, Route, End Point, Dose)

Diazepam

Rat	Oral	LD 50	710 mg/kg
Rat	Intravenous	LD 50	32 mg/kg
Rat	Intraperitoneal	LD 50	46.5 mg/kg
Mouse	Oral	LD 50	48 mg/kg
Mouse	Intravenous	LD 50	25 mg/kg

Sodium hydroxide

Mouse	IP	LD50	40 mg/kg
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11. TOXICOLOGICAL INFORMATION

Glycerol

Rat Oral LD 50 12600 mg/kg

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

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Glycerol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Diazepam

6 Week(s) Mouse Oral 0.5 mg/kg LOAEL Male reproductive system

3 Month(s) Rat Oral 100 mg/kg/day NOAEL None identified

3 Month(s) Non-human Primate Oral 5 mg/kg/day LOAEL None identified

6 Month(s) Dog Oral 20 mg/kg/day LOAEL Liver

6 Month(s) Rat Oral 162 mg/kg/day LOAEL Kidney

Glycerol

28 Day(s) Rat Oral 16800 mg/kg LOAEL Endocrine system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Diazepam

Embryo / Fetal Development Mouse Oral 100 mg/kg/day NOAEL Teratogenic, Fetotoxicity

Embryo / Fetal Development Rat Oral 100 mg/kg LOAEL Embryotoxicity

Embryo / Fetal Development Dog Oral 5 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Hamster Intraperitoneal 280 mg/kg LOAEL Teratogenic

Embryo / Fetal Development Rabbit Oral 8 mg/kg NOAEL Not Teratogenic

Glycerol

Reproductive & Fertility-Males Rat Oral 100 mg/kg LOEL Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Diazepam

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vitro Micronucleus Mouse Positive

In Vivo Chromosome Aberration Mouse Negative

In Vivo Micronucleus Mouse Negative

In Vivo Direct DNA Damage Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Diazepam

2 Year(s) Rat Liver, Tumors

2 Year(s) Mouse Not carcinogenic

2 Year(s) Hamster Not carcinogenic

80 Week(s) Male Mouse Oral 75 mg/kg/day LOAEL Malignant tumors

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11. TOXICOLOGICAL INFORMATION

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

Diazepam IARC: Group 3

At increase risk from exposure: This material has been shown to be secreted in low concentrations in human breast milk. Adverse effects on nursing infants have been seen.

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. 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 Indication of danger: Not classified

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

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



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15. REGULATORY INFORMATION

Diazepam

California Proposition 65	developmental toxicity, initial date 1/1/92
U.S. Drug Enforcement Administration:	Schedule IV Controlled Substance
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	207-122-5

Glycerol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-289-5

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb final RQ 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
R64 - May cause harm to breastfed babies.
R35 - Causes severe burns.

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

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

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