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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

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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

Contact E-Mail: pfizer-MSDS@pfizer.com

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


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
</table>

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MATERIAL SAFETY DATA SHEET

Material Name: Diazepam Injectable Emulsion
Revision date: 01-Sep-2009
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Version: 1.2

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
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<th>Classification</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>439-14-5</td>
<td>207-122-5</td>
<td>Xn;R22</td>
<td>0.5</td>
</tr>
<tr>
<td>Glycerol</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C;R35</td>
<td>**</td>
</tr>
</tbody>
</table>

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.
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: 7 µg/m³
- Bulgaria OEL - TWA: Listed

Glycerol

- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³ Listed
- 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/m³ MAK
- Greece OEL - TWA: Listed
- Ireland OEL - TWA: Listed
- OSHA - Final PELs - TWAs: 15 mg/m³ total
- Poland OEL - TWA: Listed
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed

Sodium hydroxide

- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- 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/m³
- Latvia OEL - TWA: Listed
- OSHA - Final PELs - TWAs: 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


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
Molecular Formula: Mixture
Color: No data available.
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.

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
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
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