PAGE 1

#### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: Diazepam Injection, USP

List Number: 1273, 3210, 3213

MANUFACTURER: Hospital Products Division

Abbott Laboratories

Abbott Park, Illinois 60064

EMERGENCY TELEPHONE NUMBER: 1-847-937-7970 CHEMTREC TELEPHONE NUMBER: 1-800-424-9300

# 2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME Ethyl Alcohol \*

CAS/RTECS NUMBERS 64-17-5/K6300000

OSHA-PEL 8HR TWA 1000 ppm (1900 mg/m3

STEL N/L

CEILING N/L

ACGIH-TLV 8HR TWA 1000 ppm (1880 mg/m3:

STEL N/L

CEILING N/L

OTHER 8HR TWA N/A

LIMITS STEL N/A

CEILING N/A

<sup>\*</sup> Hazardous per OSHA criteria

#### 2. COMPOSITION/INFORMATION ON INGREDIENTS, continued

```
INGREDIENT NAME
                   Benzyl Alcohol *
CAS/RTECS NUMBERS
                   100-51-6/DN3150000
OSHA-PEL 8HR TWA
                   N/L
             STEL
                   N/L
          CEILING
                   N/L
ACGIH-TLV 8HR TWA
                   N/L
             STEL
                   N/L
          CEILING
                   N/L
OTHER
          8HR TWA
                   N/A
LIMITS
             STEL
                   N/A
          CEILING
                   N/A
* Hazardous per OSHA criteria
  INGREDIENT NAME Propylene Glycol *
CAS/RTECS NUMBERS 57-55-6/TY2000000
OSHA-PEL 8HR TWA
                  N/L
             STEL
                   N/L
          CEILING
                   N/L
ACGIH-TLV 8HR TWA
                   N/L
                   N/L
             STEL
          CEILING
                   N/L
                   5 ppm total and 10 mg/m3, aerosol only (AIHA WEEL)
OTHER
          8HR TWA
LIMITS
             STEL
                   N/A
          CEILING
                  N/A
* Hazardous per OSHA criteria
  INGREDIENT NAME Diazepam *
                   439-14-5/DF1575000
CAS/RTECS NUMBERS
OSHA-PEL 8HR TWA
                   N/L
             STEL
                   N/L
          CEILING
                   N/L
ACGIH-TLV 8HR TWA
                   N/L
             STEL
                   N/L
          CEILING
                   N/L
OTHER
          8HR TWA
                   8 mcg/m3 (Abbott Laboratories Guideline).
LIMITS
             STEL
                   N/A
          CEILING N/A
* Hazardous per OSHA criteria
```

## 3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: In clinical use, this material depresses the central nervous system. Contact could irritate the skin or eyes. The active ingredient a potent drug, is toxic by ingestion and dermal exposure and is considered to be a reproductive hazard.

ROUTE(S) OF ENTRY: Skin: Unlikely

Inhalation: Unlikely Ingestion: Unlikely

INGESTION RATING: Possibly toxic

SKIN ABSORPTION RATING: Possibly toxic

INHALATION RATING: N/D

CORROSIVENESS RATING: N/D

SKIN CONTACT RATING: Possible irritant

SKIN SENSITIZATION RATING: N/D

EYE CONTACT RATING: Possible irritant

TARGET ORGANS: Central nervous system, reproductive system

CARCINOGENICITY RATING: NTP: N/L IARC: N/L OSHA: N/L

ACGIH: N/L

Alcoholic beverages are classified by IARC as Group 1 human carcinogens.

SIGNS AND SYMPTOMS: N/D. In clinical use, the most common side effects include drowsiness, fatigue and ataxia. Overdosage can result in somnolence, confusion, coma and diminished reflexes. Infrequently other central nervous system changes, constipation, nausea, incontinence, urinary retention, changes in libido, bradycardia, hypotension, blurred vision and other ocular changes, urticaria and rashes can occur.

## 3. HAZARDS INFORMATION, continued

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: N/D. Hypersensitivity to diazepam, glaucoma, respiratory or cardiovascular disease, epilepsy, concurrent use of central nervous system depressants including alcohol.

#### 4. FIRST AID MEASURES

- EYES: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring respiration, pulse and blood pressure, along with intravenous fluid and maintenance of an adequate airway, as necessary. Hypotensive effects may be treated with levarterenal or metaraminol.
- SKIN: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring respiration, pulse and blood pressure, along with intravenous fluid and maintenance of an adeuqate airway, as necessary. Hypotensive effects may be treated with levarterenal or metaraminol.
- INGESTION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring respiration, pulse and blood pressure, along with intravenous fluid and maintenance of an adequate airway, as necessary. Hypotensive effects may be treated with levarterenal or metaraminol.
- INHALATION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care, monitoring respiration, pulse and blood pressure, along with intravenous fluid and maintenance of an adequate airway, an necessary. Hypotensive effects may be treated with levarterenal or metaraminol.

PAGE 5

#### 5. FIRE FIGHTING PROCEDURES

Diazepam Injection, USP

FLASH POINT 48 C

FLASH POINT METHOD Tagliabue closed tester/tag closed tested LOWER EXPLOSIVE LIMIT(%) UPPER EXPLOSIVE LIMIT(%) N/D

AUTOIGNITION TEMPERATURE N/D

FIRE & EXPLOSION HAZARDS Due to alcohol content, this material will burn readily.

EXTINGUISHING MEDIA: Dry chemical, foam or carbon dioxide is recommended.

FIRE FIGHTING INSTRUCTIONS: Wear protective clothing and self-contained breathing apparatus.

#### ACCIDENTAL RELEASE MEASURES

SPILL OR RELEASE PROCEDURES: Absorb with suitable material, flush with water.

#### 7. HANDLING AND STORAGE

HANDLING: Protect from light and heat.

STORAGE: Store at controlled room temperature of 15-30 degrees C (59-86 degrees F).

SPECIAL PRECAUTIONS: Store away from heat. Protect from light.

#### EXPOSURE CONTROLS/PERSONAL PROTECTION 8.

ENGINEERING CONTROLS: No special provisions are required under normal conditions of use or administration.

RESPIRATORY PROTECTION: Respiratory protection is not required during normal product use. For conditions of use where unknown concentrations of vapor are generated, a self-contained breathing

PAGE 6

8. EXPOSURE CONTROLS/PERSONAL PROTECTION, continued

apparatus is recommended.

SKIN PROTECTION: Under normal product use conditions, skin protection is not anticipated. Impervious gloves are needed if skin contact is likely.

EYE PROTECTION: Eye protection is not required during typical product use conditions. Eye protection is needed if eye contact is likely.

OTHER PROTECTION: N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Clear liquid

ODOR: N/A

BOILING POINT: 98 deg. C

MELTING/FREEZING POINT: N/D

VAPOR PRESSURE (mm Hg): 43 mm Hg @ 23 C (ethyl alcohol); 0.07 mm Hg

® 20 C (propylene glycol); 1.0 mm Hg ® 58 C

(benzyl alcohol)

VAPOR DENSITY (Air=1) 1.59(ethyl alcohol); 2.6 (propylene glycol);

3.72 (benzyl alcohol)

EVAPORATION RATE N/A

BULK DENSITY N/D

SPECIFIC GRAVITY 1.0349

SOLUBILITY Slightly soluble in water

pH 6.2-6.9

VISCOSITY 5.97 centipoise

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Avoid heat, sparks and open flame.

INCOMPATIBILITIES: Oxidizing agents, acids.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon dioxide, carbon monoxide,

aldehydes or organic acids may be found.

HAZARDOUS POLYMERIZATION: N/D

#### 11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY: N/D. LD50 = 220-1520 mg/kg in rats, mice and rabbits for dizaepam (Toxic).

DERMAL TOXICITY: N/D. LD50 = 800 mg/kg in mice for diazepam (Toxic).

INHALATION TOXICITY: N/D

CORROSIVENESS: N/D

DERMAL IRRITATION: N/D. Propylene glycol, benzyl alcohol and ethyl alcohol are mild to severe skin irritants in man or rabbits and guinea pigs.

OCULAR IRRITATION: N/D. Ethylene alcohol, propylene glycol and benzyl alcohol are mild to severe eye irritatant in rabbits.

DERMAL SENSITIZATION: N/D

SPECIAL TARGET ORGAN EFFECTS: N/D. In clinical use, diazepam effects the central nervous system producing sedation and calming. Use of diazepam during pregnancy is associated with an increased risk or congenital malformations. Prolonged use results in tolerance and psychological and physical dependence. Ethyl alcohol is known to produce liver injury, is reported to be mutagenic and is teratogenic in humans.

CARCINOGENICITY INFORMATION: N/D

12. ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/D

13. DISPOSAL CONSIDERATIONS

PAGE 8

# 14. TRANSPORTATION INFORMATION

Not Regulated DOT STATUS

PROPER SHIPPING NAME N/A

HAZARD CLASS N/A

UN NUMBER N/A

PACKING GROUP N/A

RE PORTABLE QUANTITY N/A

IATA/ICAO STATUS Not Regulated

PROPER SHIPPING NAME N/A

HAZARD CLASS N/A

UN NUMBER N/A

PACKING GROUP N/A

REPORTABLE QUANTITY N/A

Not Regulated IMO STATUS

PROPER SHIPPING NAME N/A

HAZARD CLASS N/A

UN NUMBER N/A

PACKING GROUP N/A

REPORTABLE QUANTITY N/A FLASH POINT 48 C

15. REGULATORY INFORMATION

TSCA STATUS: N/A

CERCLA STATUS: N/L

SARA STATUS: N/L

RCRA STATUS: N/L

PROP 65 (CA): N/L

Diazepam Injection, USP

ISSUED 09/01/99

### 16. OTHER INFORMATION

LEGEND: N/A = Not Applicable

N/D = Not Determined

N/L = Not Listed

L = Listed

C = Ceiling

S = Short-term

(R) = Registered Trademark of Abbott Laboratories

(TM) = Registered Trademark of Abbott Laboratories

The information and recommendations contained herein are based upon information believed to be reliable. However, Abbott Laboratories does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform with actual conditions of usage may be required. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages arising from the use of these data. No freedom from infringement of any patent, copyright or trademark is to be inferred.

APPROVED BY: DLF