YEDC641

Product Name: Diazepam Injection, USP
Issued: 14-Feb-2003

5106-3

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Hospital Products Division
200 Abbott Park Rd.
Abbott Park, Illinois 60064 - 6135

Customer Service Telephone: HPD : 1-800-222-6883

Emergency Telephone: CHEMTREC: 1-800-424-9300

Product Name: Diazepam Injection, USP

Product Use: Benzadiazepine contained in glass vials for parenteral use to relieve anxiety and promote sedation. Low clinical dose of 4 mg.

List Number: 1273, 3210, 3213.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Diazepam 439-14-5	0.5	Not Listed	Not Listed	Not Applicable	8 mcg/m^3 TWA	None
Benzyl Alcohol 100-51-6	1.5	Not Listed	Not Listed	10 ppm TWA; 44.2 mg/m^3 TWA	Not Applicable	None
Propylene Glycol 57-55-6	40	Not Listed	Not Listed	50 ppm TWA (total); 10 mg/m^3 TWA (aerosol only)	Not Applicable	None
Ethyl Alcohol 64-17-5	10	1000 ppm TWA; 1900 mg/m^3 TWA	1000 ppm TWA	Not Applicable	Not Applicable	None

Notes:
OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

3. HAZARDS IDENTIFICATION

Emergency Overview:
Clear solution.
Odorless.
Reproductive hazard. Potent drug.

Routes of Exposure:
Oral: Unlikely (intact container)
Dermal: Unlikely (intact container)

Inhalation: Unlikely (intact container)

Hazard Information:

Ingestion Rating: Possibly Toxic
Skin Absorption Rating: Possibly Toxic
Inhalation Rating: Possibly Toxic
Corrosiveness Rating: Not determined.
Skin Contact Rating: Possible Irritant.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Possible Irritant.
Target Organs: Nervous System , Respiratory System , Cardiovascular System , DNA , Reproductive System.

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Diazepam	0.5	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	1.5	Not Listed	Not Listed	Not Listed	Not Listed
Propylene Glycol	40	Not Listed	Not Listed	Not Listed	Not Listed
Ethyl Alcohol	10	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating:

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: nausea, diarrhea, drowsiness, ataxia. Clinical overdose may result in the following: confusion, coma, muscle weakness. Reported to cause the following: central nervous system depression, constipation, incoordination, decreased blood pressure, rash, gastrointestinal upset, visual impairment, altered libido, nausea.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any preexisting ailments in the following organs: central nervous system, cardiovascular system, respiratory system, male reproductive system, female reproductive system. Pregnancy. Concurrent intake of depressants like alcohol.

4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. Seek immediate medical attention. Provide symptomatic/supportive care as necessary.

Notes To Physician: Provide replacement fluids and electrolytes as required. Monitor central nervous system, cardiovascular and respiratory systems as necessary. Hypotensive effect may be treated with levarterenal or metaraminol.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:

Flash Point (°C): 48
Flash Point Method: Tag Closed Cup (TCC)
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Use alcohol foam, carbon dioxide or dry chemical. Water may be ineffective.

Special Protective Equipment: Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

Special Exposure Hazards: Due to alcoholic content, this material will burn readily.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Absorb with suitable material. Flush with water.

Personal Precautions: Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Protect from light. Protect from heat.

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

Special Precautions: Protect from light. Avoid excessive heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use. An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Eye protection not required during typical product use conditions. Recommended if eye contact is likely.

Gloves: Impervious gloves.

Other Personal Protection Data: NA

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear solution.
Odor: Odorless.

Boiling Point @ 760 mm Hg (°C): 98 Deg. C
Melting/Freezing Point (°C): Not determined.
Vapor Pressure (mm Hg) 43 mm Hg @ 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)
Bulk Density at 20°C: Not determined.
Solubility: Slightly soluble in: water.
Specific Gravity: 1.0349
pH: 6.2 - 6.9
Viscosity (centipoise): 5.97

10. STABILITY AND REACTIVITY

Chemical Stability: Avoid exposure to heat, sparks and open flame.

Self-Heating Tendency: Not determined.

Materials to Avoid: Acids. Oxidizers.

Hazardous Decomposition Products: CO2, CO, aldehydes, organic acids.

Hazardous Polymerization: Not determined.

Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Diazepam	0.5	LD50 =	48 249 328 500	mg/kg	Mice Rats Rabbits Mammals
Benzyl Alcohol	1.5	LD50 =	1040-3100	mg/kg	Animals
Propylene Glycol	40	LD50 =	10,000-33,700	mg/kg	Animals
Ethyl Alcohol	10	LD50 =	5560-13,700	mg/kg	Guinea Pigs Rats Mice Rabbits

Acute Toxicity - Dermal: Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Diazepam	0.5	LD50 =	800	mg/kg	Mice
Benzyl Alcohol	1.5	LD50 =	2000	mg/kg	Rabbits
Propylene Glycol	40	LD50 =	20,800	mg/kg	Rabbits
Ethyl Alcohol	10	LD50 =	20000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined. Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Benzyl Alcohol	1.5	LC 50 =	2000	ppm	Rats
Ethyl Alcohol	10	LC 50 =	20000	ppm	Rats

Other Toxicology Data: Data for component (s) given below:

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Diazepam	0.5	LD50 (ip) =	37 465	mg/kg	Mice Rats	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined. Major ingredient: Reported to produce skin irritation in humans.

Eye Irritation: Not determined. Major ingredient: Reported to produce eye irritation.

Sensitization: Not determined.

Target Organ Effects: Clinical dose is less than (<) 10 mg/day. In clinical use target organ effects include: respiratory system, cardiovascular system, central nervous system, DNA, female reproductive system, male reproductive system, fetus.

In clinical use, diazepam effects the central nervous system producing sedation and calming. Use of diazepam during pregnancy is associated with an increased risk of congenital malformations. Prolonged use can result in tolerance and psychological and physical dependence.

Reproductive Effects: In animals adverse reproductive effects include: fetal abnormalities.

Ethyl Alcohol : Use of alcohol during pregnancy can lead to retarded growth, development delays and abnormalities (fetal alcohol syndrome).

Carcinogenicity: Not determined. Data for components given below.

Ingredients	Percent	Site of Tumors	Species	Dosage	Units	Route	Duration
Benzyl Alcohol	1.5	None.	Animals	200	mg/kg	Oral	Unspecified

Mutagenicity: Data for component (s) given below.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Diazepam	0.5	Positive	No Data.	Positive	Positive

Notes:
1. **ALD: Approximate lethal dosage**
2. **LC50: Concentration in air that produces 50% mortality**
3. **LD50: Oral or dermal dosage that produces 50% mortality**

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: None.

Notes:
1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Disposal should be made in accordance with federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT:

Status: This material is an aqueous solution per 49 CFR 173.150 (e).

ICAO/IATA:

Status: Regulated.
Proper Shipping Name: Flammable liquids, N.O.S.
Hazard Class: 3
UN ID: UN1993
Packing Group: III

IMDG:

Status: Regulated.
Dangerous Goods Description: Flammable liquids, N.O.S.
Hazard Class: 3
UN ID: UN1993
Packing Group: III
EMS No.: F-E, S-E

TDG (Canada):

Status: Not determined.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Diazepam	0.5	No	Not Applicable	Not applicable
Benzyl Alcohol	1.5	No	Not Applicable	Not applicable
Propylene Glycol	40	No	Not Applicable	Not applicable
Ethyl Alcohol	10	No	Not Applicable	Not applicable

SARA 311/312 Hazard Catagories:

Immediate Health: Not determined.
Delayed Health: Not determined.
Fire: Not determined.
Sudden Pressure: Not determined.
Reactivity: Not determined.

TSCA Inventory Status: Not determined.

CERCLA Status: Not determined.

Product Name: **Diazepam Injection, USP**
Issued: **06-Feb-2002**

RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Ingredients	Percent	Proposition 65 Listed Materials
Diazepam	0.5	Listed Reproductive Toxicity;January 1,1992
Ethyl Alcohol	10	Developmental toxicity (when in alcoholic beverages); initial date 10/1/87.

EC HAZARD CLASSIFICATION:

Category of Danger: None

Indication of danger: Not dangerous goods

ICH Classification: Not determined.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: Not determined.

Notes:

1. SARA = Superfund Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. ICH = International Committee for Harmonization.

16. OTHER INFORMATION

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